

DEPARTMENT OF HEALTH AND SOCIAL SERVICES
DIVISION OF LONG TERM CARE RESIDENTS PROTECTION
Statutory Authority: 16 Delaware Code,
Section 3006A (16 Del.C. §3006A)

ORDER

FINAL

Regulations for Assisted Living Facilities

Nature of the Proceedings

The Department of Health and Social Services, Division of Long Term Care Residents Protection (DLTCRP) initiated proceedings in accordance with 29 Del.C. Ch. 101 to amend the regulations for Assisted Living Facilities. The amendments relate to incident reporting by facilities, requirements for electrical generators and an exemption for subcutaneous venous ports from the prohibition against the admission of residents with central lines. On May 1, 2004, DLTCRP published proposed amendments to the regulations in the Register of Regulations and received written and verbal comments at public hearings on June 2 and June 3, 2004.

Upon review of the comments received, the Division of Long Term Care Residents Protection has revised the proposed regulations pertaining to requirements for electrical generators. Those revised proposed regulations appear elsewhere in this edition of the Register and will be the subject of a further public hearing. Comments received at the June public hearings regarding requirements for electrical generators will be discussed when those regulations are published as final regulations.

The proposed regulations relating to incident reporting and the exemption for subcutaneous venous ports are attached and are being promulgated as final regulations. A discussion of the comments received during the June public hearings is in the accompanying Summary of Evidence.

Findings of Fact

The Department of Health and Social Services finds that the proposed regulations, as set forth in the attached copy, should be adopted as final regulations. Therefore, it is ordered that the proposed Regulations for Assisted Living Facilities are adopted effective July 10, 2004.

Vincent P. Meconi,
Secretary, Department of Health
and Social Services
Date of Signature 6.15.04

Summary of Evidence

Comments on the proposed regulations have been received and evaluated as follows:

One commenter referencing 63.1807(g) said that when incident reports are made, there should be a double check to make sure that written comments follow so that the reports are not lost. We believe that the section the commenter is actually referencing is 63.1806. It should be noted that the Division maintains records of all reports that are made in any form.

Two comments were received in reference to provisions regarding incident reporting, including reporting of power outages, which allow facilities eight hours to report to the Division. One commenter said that the timeframe was too long. The other commenter said that the timeframe was too short. The eight-hour timeframe is retained in the regulations as a reasonable amount of time.

Another comment said that persons with subcutaneous ports should not be allowed in assisted living facilities. We believe that an exception for this particular type of central line is appropriate both because a subcutaneous port is not subject to being accidentally dislodged and because the facility staff is not required or permitted to provide any care to a subcutaneous port, the care of which is handled by health care professionals outside of the facility.

Finally, two commenters sought clarification as to who determines which rooms in a facility will be selected for congregate use during a power outage. This decision is left to the discretion of each facility. Note also that a "room"

may be construed to include a contained common area.

Regulations for Assisted Living Facilities

SECTION 63.0 PURPOSE

The Department of Health and Social Services is issuing these regulations to promote and ensure the health, safety, and well-being of all residents of assisted living facilities. These regulations are also meant to ensure that service providers will be accountable to their residents and the Department, and to differentiate assisted living care from skilled nursing care. The essential nature of assisted living is to offer living arrangements to medically stable persons who do not require skilled nursing services and supervision. The regulations establish the minimal acceptable level of services for residents of assisted living facilities.

SECTION 63.1 AUTHORITY AND APPLICABILITY

These regulations are promulgated in accordance with 16 **Del.C.** Chapter 11 and shall apply to any facility providing assisted living to elderly individuals or adults with disabilities. The term “assisted living” shall not be used as part of the official name of any facility in this State unless the facility has been so licensed by the Department of Health and Social Services.

SECTION 63.2 GLOSSARY OF TERMS

63.201 Activities of Daily Living (“ADLs”) - Normal daily activities including but not limited to ambulating, transferring, range of motion, grooming, bathing, dressing, eating, and toileting.

63.202 Administration of Medication - The process whereby a single dose of a prescribed drug is given to a resident by an authorized licensed person, as described in 24 **Del.C.** §1902.

63.203 Assisted Living - A special combination of housing, supportive services, supervision, personalized assistance and health care designed to respond to the individual needs of those who need help with activities of daily living and/or instrumental activities of daily living.

63.204 Assisted Living Facility – A licensed entity that provides the services described in 63.203.

63.205 Assistive Technology - Any item, piece of equipment or product system whether acquired commercially off the shelf, modified, or customized that is used to increase or improve functional capabilities of adults with disabilities.

63.206 Assistance With Self-Administration of Medication (“AWSAM”) - Help with medication provided by facility personnel who are not nurses or nurse practitioners but who have successfully completed a Board of Nursing-approved medication training program in accordance with the Delaware Nurse Practice Act, 24 **Del.C.** Ch. 19, and applicable rules and regulations. Help with medication includes holding the container, opening the container, and assisting the resident in taking the medication, other than by injection, following the directions of the original container, and documenting in the medication log that each medication has been taken by the residents.

63.207 Communicable Disease - An illness caused by a microorganism or its toxin characterized by spread from host to victim by air, contact, blood, or bodily fluids.

63.208 Contract – A legally binding written agreement between the facility and the resident which enumerates all charges for services, materials, and equipment, as well as non-financial obligations of both parties, as specified in these regulations.

63.209 Cuing - The act of guiding residents, verbally or by gestures, to facilitate memory and/or organize verbal and/or behavioral responses.

63.210 Department - Department of Health and Social Services.

63.211 Division - Division of Long Term Care Residents Protection.

63.212 Durable Medical Equipment - Equipment capable of withstanding repeated use, primarily and customarily used to serve a medical purpose, generally not useful to a person in the absence of an illness or injury, and needed to maintain the resident in the facility, e.g., wheelchairs, hospital beds, oxygen tanks.

63.213 Homelike - Having the qualities of a home, including privacy, comfortable surroundings supported by the use of residential building materials and furnishings, and the opportunity to modify one’s living area to suit one’s individual preferences, in accordance with the facility’s policies. A homelike environment provides residents with an opportunity for self-expression and encourages interaction with community, family, and friends.

63.214 Hospice - An agency licensed by the State of Delaware that provides palliative and supportive medical and other health services to terminally ill residents and their families.

63.215 Incident - An occurrence or event, a record of which must be maintained in facility files, ~~that results or might result in harm to a resident. Incident includes alleged abuse, neglect, mistreatment and financial exploitation; incidents of unknown source which might be attributable to abuse, neglect or mistreatment; all deaths; falls; and errors or omissions in medication/treatment.~~ which includes all reportable incidents and the additional occurrences or events listed in Section 63.1805 of these regulations. (Also see Reportable Incident, 63.222.)

63.216 Individual Living Unit - A separate dwelling area within an assisted living facility which has living and sleeping space for one or more residents, as prescribed in these regulations.

63.217 Instrumental Activities of Daily Living (“IADLs”) - Home management skills, such as shopping for food and personal items, preparing meals, or handling money.

63.218 Managed/Negotiated Risk Agreement – A signed document between the resident and the facility, and any other involved party, which describes mutually agreeable action balancing resident choice and independence with the health and safety of the resident or others.

63.219 Medication Log – A written document in which licensed personnel and unlicensed personnel who have completed AWSAM training record administration/ assistance with the resident’s medications. The log shall list the resident’s name; date of birth; allergies; reason the medication is given; prescribing practitioner and phone number; special instructions; and the dosage, route(s), and time(s), for all medications received/taken with staff administration or staff assistance. The log is signed/initialed by a staff member after each resident has received/taken the appropriate medication, or when the medication was not taken/given as prescribed.

63.220 Medication Management by an Adult Family Member/Support Person – Any help with prescription or non-prescription medication provided by an adult family member/support person, as identified in the resident’s contract and service agreement.

63.221 Personal Care Supplies - Those supplies, often disposable, used by a resident, such as incontinence products and hygiene supplies.

63.222 Reportable Incident - An occurrence or event which must be reported ~~at once~~ 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 as those terms are defined in 16 Del. Code §1131. Reportable incident also includes ~~an incident of unknown source which might be attributable to abuse, neglect or mistreatment; all deaths; falls with injuries; and significant errors or omissions in medication/treatment which cause the resident discomfort or jeopardize the resident’s health and safety.~~ an occurrence or event listed in Section 63.1807 of these regulations. (Also see Incident, 63.215.)

63.223 Representative - A person acting on behalf of the resident pursuant to Delaware law.

63.224 Resident - An individual 18 years old or older who lives in an assisted living facility. Where appropriate in the context of these regulations, “resident” as used herein includes an authorized representative as defined in 63.223.

63.225 Resident Assessment - Evaluation of a resident’s physical, medical, and psychosocial status as documented in a Uniform Assessment Instrument (UAI), by a registered nurse.

63.226 Resident Assistant – Any unlicensed direct caregiver who, under the supervision of the assisted living director or director of health services, assists the resident with personal needs and monitors the activities of the resident while on the premises to ensure his/her health, safety, and well-being.

63.227 Secretary - Secretary of the Department of Health and Social Services.

63.228 Service Agreement - A written document developed with each resident which describes what services will be provided, who will provide the services, when the services will be provided, how the services will be provided, and, if applicable, the expected outcome.

63.229 Shared Responsibility - The concept that residents and assisted living facilities share responsibility for planning and decision-making affecting the resident.

63.230 Significant Change - A major deterioration or improvement in a resident’s health status or ability to perform ADLs; a major alteration in behavior or mood resulting in ongoing problematic behavior or the elimination of that behavior on a sustained basis. Significant change does not include ordinary, day-to-day fluctuations in health status, functioning, and behavior, or a short-term illness such as a cold, unless these fluctuations continue to recur, nor does it include deterioration that will normally resolve without further intervention.

63.231 Social Services - Services provided to assist residents in maintaining or improving their ability to manage their everyday physical, mental and psychosocial needs.

63.232 Third-Party Provider - Any party, including a family member, other than the assisted living facility which furnishes services/supplies to a resident.

63.233 Uniform Assessment Instrument (“UAI”) - A document setting forth standardized criteria developed by the Division to assess each resident’s functional, cognitive, physical, medical, and psychosocial needs and status. The assisted living facility shall be required to use the UAI to evaluate each resident on both an initial and ongoing

basis in accordance with these regulations.

SECTION 63.3 LICENSING REQUIREMENTS AND PROCEDURES

63.301 No entity shall hold itself out as being an assisted living facility unless such entity has been duly licensed under these regulations and in accordance with state law. The Secretary or his/her designee shall issue a provisional or annual license for a specified number of beds.

63.302 Procedures for assisted living facility applications and for issuance, posting, and renewal of licenses shall be in accordance with 16 **Del.C.** Ch. 11, Subchapter I., Licensing By The State.

63.303 Inspections and monitoring shall be conducted in accordance with 16 **Del.C.** Ch. 11, Subchapter I., Licensing By The State.

63.304 Upon receipt of written notice of a violation of these regulations, the assisted living facility shall submit a written plan of action to correct deficiencies cited within 10 working days or such other time period as may be required by the Department. The plan of action shall address corrective actions to be taken and include all measures and completion dates to prevent their recurrence: 1) how the corrective action will be accomplished for those residents found to have been affected by the deficient practice; 2) how the facility will identify other residents having the potential to be affected by the same deficient practice; 3) what measures will be put into place or systemic changes made to ensure that the deficient practice will not recur; and 4) how the facility will monitor its corrective actions to ensure that the deficient practice is being corrected and will not recur, i.e., what program will be put into place to monitor the continued effectiveness of the systemic changes.

63.305 The Department may impose civil money penalties and/or other enforcement remedies in accordance with the procedures outlined in 16 **Del.C.**, Chapter 11, Subchapter I., Licensing By The State.

63.306 The Department may suspend or revoke a license, or refuse to renew it, in accordance with 16 **Del.C.**, Ch. 11, Subchapter I., Licensing By The State.

63.307 Separate licenses are required for agencies 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. Under conditions of assignment or transfer of ownership, a new license shall be required.

63.308 If a facility or part of a facility plans to close:

A. The assisted living facility shall notify representatives of the appropriate state agencies of the plan of closure at least 90 days before the planned closure.

B. The facility staff must notify each resident advising him/her of the action in progress at least 90 days before the planned closure.

C. The resident must be given the opportunity to designate a preference for a specific facility or for other arrangements.

D. The assisted living facility must arrange for the relocation to other facilities in the area in accordance with the residents' preference, if possible.

E. Any applicant for admission to the assisted living facility shall be advised of the planned closure date.

F. All residents' records and any medications must accompany the residents to their new residences.

63.309 The Department may adopt, amend or repeal regulations governing the operation of the agencies defined in 16 **Del.C.**, Ch. 11, Subchapter I., Licensing By The State.

SECTION 63.4 GENERAL REQUIREMENTS

63.401 All written information provided by the assisted living facility shall be accurate, precise, easily understood and readable by a resident, and in compliance with all applicable laws.

63.402 All records maintained by the assisted living facility shall at all times be open to inspection and copying by the authorized representatives of the Department, as well as other agencies as required by state and federal laws and regulations. Such records shall be made available in accordance with 16 **Del.C.**, Ch. 11, Subchapter I., Licensing By The State.

63.403 The assisted living facility shall adopt internal written policies and procedures pursuant to these regulations. No policies shall be adopted by the assisted living facility which are in conflict with these regulations.

63.404 The assisted living facility shall establish and adhere to written policies and procedures regarding the rights and responsibilities of residents, and these policies and procedures shall be made available to authorized representatives of the Department, facility staff, and residents.

63.405 The assisted living facility shall develop and adhere to policies and procedures to prevent residents with

diagnosed memory impairment from wandering away from safe areas. However, residents may be permitted to wander safely within the perimeter of a secured unit.

63.406 The assisted living facility shall arrange for emergency transportation and care.

63.407 Inspection summaries and compliance history information shall be posted by the facility in accordance with 16 Del.C., Chapter 11, Subchapter I., Licensing By The State.

63.408 An assisted living facility shall recognize the authority of a representative acting on the resident's behalf pursuant to Delaware law, as long as such representative does not exceed his/her authority. The facility shall request and keep on file any documents such as an advance directive, living will, do not resuscitate, and power(s) of attorney.

63.409 An assisted living facility shall not admit, provide services to, or permit the provision of services to individuals who, as established by the resident assessment:

A. Require care by a nurse that is more than intermittent or for more than a limited period of time;
B. Require skilled monitoring, testing, and aggressive adjustment of medications and treatments where there is the presence of, or reasonable potential of, an acute episode unless there is an RN to provide appropriate care;
C. Require monitoring of a chronic medical condition that is not essentially stabilized through available medications and treatments;

D. Are bedridden for more than 14 days;

E. Have developed stage three or four skin ulcers;

F. Require a ventilator;

G. Require treatment for a disease or condition which requires more than contact isolation;

H. Have an unstable tracheotomy or have a stable tracheotomy of less than 6 months' duration;

I. Have an unstable peg tube;

J. Require an IV or central line; with an exception for a completely covered subcutaneously implanted venous port provided the assisted living facility meets the following standards:

1. Facility records shall include the type, purpose and site of the port, the insertion date, and the last date medication was administered or the port flushed.

2. The facility shall document the presence of the port on the Uniform Assessment Instrument, the service plan, interagency referrals and any facility reports.

3. The facility shall not permit the provision of care to the port or surrounding area, the administration of medication or the flushing of the port or the surgical removal of the port within the facility by facility staff, physicians or third party providers;

K. Wander such that the assisted living facility would be unable to provide adequate supervision and/or security arrangements;

L. Exhibit behaviors that present a threat to the health or safety of themselves or others, such that the assisted living facility would be unable to eliminate the threat either through immediate discharge or use of immediate appropriate treatment modalities with measurable documented progress within 45 days; and

M. Are socially inappropriate as determined by the assisted living facility such that the facility would be unable to manage the behavior after documented, reasonable efforts such as clinical assessments and counseling for a period of no more than 60 days.

63.410 The provisions of Section 63.409 above do not apply to residents under the care of a Hospice program licensed by the Department as long as the Hospice program provides written assurance that, in conjunction with care provided by the assisted living facility, all of the resident's needs will be met without placing other residents at risk.

SECTION 63.5 RESIDENT WAIVERS

63.501 An assisted living facility may request a resident-specific waiver so that it may serve a current resident who temporarily requires care otherwise excluded in section 63.409. A waiver request shall contain documentation by a physician stating that the resident's condition is expected to improve within 90 days.

63.502 The facility shall provide interim needed services by appropriate health care professionals while any waiver request is pending.

63.503 The assisted living facility shall submit in writing a request for a waiver, which shall include the following information:

A. An explanation of why the assisted living facility is seeking the waiver, to include physician documentation and a service agreement which details how staff will provide care;

B. An explanation of why denial of the waiver will impose a substantial hardship for the resident;

C. An explanation of why the waiver will not adversely affect the resident for whom the waiver is sought or other residents; and

D. The duration of the waiver, not to exceed 90 days for each incident or condition.

63.504 In evaluating a waiver request submitted under this regulation, the Department shall review the

statements in the application and may:

- A. Inspect the assisted living facility;
- B. Confer with the Assisted Living Director or his/her designee;
- C. Discuss the request with the resident to determine whether he/she believes a waiver is in his/her best interest; and/or
- D. Review other waivers currently in place at the assisted living facility.

63.505 The Department shall issue a written decision on a waiver request submitted pursuant to these regulations within 5 business days of receipt of the request. If the Department grants the waiver, the written decision shall include the waiver's duration. If the Department denies the waiver, the written decision shall explain the reason(s) for the denial. The assisted living facility may submit a revised waiver request no later than five days after the receipt of the denial. While the second waiver request is pending, the facility shall provide needed services by health care professionals as outlined in the second waiver request.

63.506 If an assisted living facility violates any condition of a waiver, or if it appears to the Department that the health or safety of residents will be adversely affected by the continuation of a waiver, the Department may revoke it. The revocation may be appealed; however, discharge procedures in accordance with Regulation 906E. shall be commenced immediately.

SECTION 63.6 SPECIALIZED CARE FOR MEMORY IMPAIRMENT

63.601 Any assisted living facility which offers to provide specialized care for residents with memory impairment shall be required to disclose its policies and procedures which describe the form of care or treatment provided, in addition to that care and treatment required by the rules and regulations herein.

63.602 Said disclosure shall be made to the Department and to any person seeking specialized care for memory impairment in an assisted living facility.

63.603 The information disclosed shall explain the additional care that is provided in each of the following areas:

- A. Philosophy: a written statement of the agency's overall philosophy and mission which reflects the needs of residents affected by memory impairment;
- B. Resident Population: a description of the resident population to be served; the service agreement and its implementation;
- C. Pre-Admission, Admission & Discharge: the process and criteria for placement, transfer or discharge from this specialized care;
- D. Assessment, Care Planning & Implementation: the process used for assessment and establishing and updating the service agreement and its implementation,
- E. Staffing Plan & Training Policies: staffing plan, orientation, and regular in-service education for specialized care;
- F. Physical Environment: the physical environment and design features, including security systems, appropriate to support the functioning of adults with memory impairment;
- G. Resident Activities: the frequency and types of resident activities;
- H. Family Role in Care: the family involvement and family support programs;
- I. Psychosocial Services: the process for addressing the mental health, behavior management, and social functioning needs of the resident;
- J. Nutrition/Hydration: the frequency and types of nutrition and hydration services provided; and
- K. Program Costs: the cost of care and any additional fees.

63.604 Any significant changes in the information provided by the assisted living facility shall be reported to the Department at the time the changes are made.

SECTION 63.7 MEDICATION MANAGEMENT

63.701 An assisted living facility shall establish and adhere to written medication policies and procedures which shall address:

- A. Obtaining and refilling medication;
- B. Storing and controlling medication;
- C. Disposing of medication; and
- D. Administration of medication, self-administration of medication, assistance with self-administration of medication, and medication management by an adult family member/support person.

- E. Provision for a quarterly pharmacy review which shall include:
 - 1. Assisting the facility with the development and implementation of medication-related policies and procedures;
 - 2. Physical inspection of the medication storage areas;
 - 3. Review of each resident's medication regimen with written reports noting any identified irregularities or areas of concern.

63.702 Each assisted living facility shall have a drug reference guide, with a copyright date no older than 2 years, available and accessible for use by employees.

63.703 Medication stored by the assisted living facility shall be stored and controlled as follows:

- A. Medication shall be stored in a locked container, cabinet, or area that is only accessible to authorized personnel;
- B. Medication that is not in locked storage shall not be left unattended and shall not be accessible to unauthorized personnel;
- C. Medication shall be stored in the original labeled container;
- D. A bathroom or laundry room shall not be used for medication storage; and
- E. All expired or discontinued medication, including those of deceased residents, shall be disposed of according to the assisted living facility's medication policies and procedures.

63.704 Residents who self-administer medication shall be provided with a locked container.

63.705 A separate medication log must be maintained for each resident documenting administration of medication by staff and staff assistance with self-administration.

63.706 Within 30 days after a resident's admission and concurrent with all UAI-based assessments, the assisted living facility shall arrange for an on-site review by an RN of the resident's medication regime if he or she self-administers medication. The purpose of the on-site review is to assess the resident's cognitive and physical ability to self-administer medication or the need for assistance with or staff administration of medication.

63.707 The assisted living facility shall ensure that the review required by section 63.706 is documented in the resident's records, including any recommendations given by the reviewer.

63.708 Concurrently with all UAI-based assessments, the assisted living facility shall arrange for an on-site medication review by a registered nurse, for residents who need assistance with self-administration or staff administration of medication, to ensure that:

- A. Medications are properly labeled, stored and maintained;
- B. Each resident receives the medications that have been specifically prescribed in the manner that has been ordered;
- C. The desired effect of each medication is achieved, and if not, that the appropriate authorized prescriber is so informed;
- D. Any undesired side effects, adverse drug reactions, and medication errors are identified and reported to the appropriate authorized prescriber; and
- E. Any unresolved discrepancy of controlled substances shall be reported to the Delaware Office of Narcotics and Dangerous Drugs.

63.709 Records shall be kept on file at the facility for those who have completed the AWSAM course which is required by 24 **Del.C.**, Chapter 19 for those who assist the residents with self-administration of medication.

63.710 Each assisted living facility shall complete an annual AWSAM report on the form provided by the Board of Nursing. The report must be submitted pursuant to the Delaware Nurse Practice Act, 24 **Del.C.**, Chapter 19.

SECTION 63.8 INFECTION CONTROL

63.801 The assisted living facility shall establish written procedures to be followed in the event that a resident with a communicable disease is admitted or an episode of communicable disease occurs. It is the responsibility of the assisted living facility to see that:

- A. The necessary precautions stated in the written procedures are followed; and
- B. All rules of the Delaware Division of Public Health are followed so there is minimal danger of transmission to staff and residents.

63.802 Any resident found to have active tuberculosis in an infectious stage may not continue to reside in an assisted living facility.

63.803 A resident, when suspected or diagnosed as having a communicable disease, shall be placed on the appropriate isolation or precaution as recommended for that disease by the Centers for Disease Control. Those with a communicable disease which has been determined by the Director of the Division of Public Health to be a health hazard to visitors, staff, and other residents shall be placed on isolation care until they can be moved to an appropriate room or transferred.

63.804 The admission or occurrence of a resident with a notifiable disease within an assisted living facility shall be reported to the County Public Health Administrator. See Appendix A.

63.805 The assisted living facility shall have on file results of tuberculin tests:

- 1) performed annually for all employees and
- 2) performed on all newly admitted residents. The tuberculin test to be used is the Mantoux test containing 5 TU-PPD stabilized with Tween, injected intradermally, using a needle and syringe, usually on the volar surface of the forearm. Persons found to have a significant reaction (defined as 10 mm of induration or greater) to tests shall be reported to the Division of Public Health and managed according to recommended medical practice. A tuberculin test as specified, done within the twelve months prior to employment, or a chest x-ray showing no evidence of active tuberculosis shall satisfy this requirement for asymptomatic individuals. A report of this skin test shall be kept on file.

63.806 The assisted living facility 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. All residents who refuse to be vaccinated against influenza must be fully informed by the facility of the health risks involved. The reason for the refusal shall be documented in the resident's medical record.

63.807 The assisted living facility shall have on file evidence of vaccination against pneumococcal pneumonia for all residents older than 65 years and as recommended by the Immunization Practice Advisory Committee of the Centers for Disease Control, unless medically contraindicated. All residents who refuse to be vaccinated against pneumococcal pneumonia must be fully informed by the facility of the health risks involved. The reason for the refusal shall be documented in the resident's medical record.

63.808 The assisted living facility shall have policies and procedures for infection control as it pertains to staff, residents, and visitors.

63.809 All assisted living facility staff shall be required to use Standard Precautions.

SECTION 63.9 RESIDENT APPLICATIONS AND CONTRACTS

63.901 The assisted living facility shall have a written application process and provide clear reasons in writing if an applicant is rejected.

63.902 The assisted living facility shall recommend review of the contract by an attorney or other representative chosen by the resident.

63.903 Prior to executing the contract, each assisted living facility shall provide to the prospective resident a complete statement enumerating all charges for services, materials and equipment which shall, or may be, furnished to the resident during the period of occupancy.

63.904 The resident shall sign a contract within 3 business days after admission that:

- A. Is a clear and complete reflection of commitments agreed to by the parties and the actual practices that will occur in the assisted living program;
- B. Is accurate, precise, legible, and written in plain language; and
- C. Conforms to all relevant state and local laws and regulations.

63.905 The assisted living facility shall retain the contract on-site and make it available for review by the Department or its designee. The facility shall also provide a copy to the resident.

63.906 The contract or service agreement shall include, at a minimum, the following non-financial provisions:

- A. A listing of basic and optional services provided by the assisted living facility including the availability of licensed nursing staff;
- B. A listing of optional services that may be provided by third parties;
- C. A statement of the resident's rights, as set forth in 16 Del.C. Chapter 11, Subchapter II and an explanation of the assisted living facility's grievance procedures;
- D. Occupancy provisions, including:
 1. Policies regarding bed and room assignment, including the specific room and bed assigned to the resident at the time of admission;
 2. Policies regarding residents modifying their living area;
 3. Procedures to be followed when the assisted living facility temporarily or permanently changes the resident's accommodation by:
 - a. Relocating the resident within the facility;
 - b. Making a change in roommate assignment; and

- c. Increasing or decreasing the number of individuals occupying a room.
 - 4. Procedures to be followed in transferring the resident to another facility;
 - 5. Security procedures which the licensee shall implement to protect the resident and the resident's property;
 - 6. The staff's right to enter a resident's room;
 - 7. The resident's rights and obligations concerning use of the facility, including common areas;
 - 8. The assisted living facility's policy in case of unavoidable or optional absences such as hospitalizations, recuperative stays in other settings, or vacation, and payment terms;
 - 9. Provisions for interim service in the event of an emergency; and
 - 10. An acknowledgment that the resident has reviewed all assisted living facility rules, requirements, restrictions, or special conditions that the facility will impose on the resident.
 - E. Discharge/temporary absence policies and procedures, including:
 - 1. Those actions, circumstances, or conditions that temporarily disqualify individuals from continued residence in the assisted living facility or may result in the resident's discharge from the facility;
 - 2. The procedures which the assisted living facility shall follow if it intends to discharge a resident and thereby terminate the contract, including a provision under which the assisted living facility shall give at least 30 days notice to the resident before the effective date of the discharge and termination of the contract, except in the case of a health emergency or substantial risk to the health and safety of the other residents or facility staff;
 - 3. The procedures which the resident shall follow if the resident wishes to terminate the contract, including a provision that the resident, or appropriate representative, shall give at least 30 days notice to the assisted living facility before the effective date of the termination, except in the case of a health emergency;
 - 4. The procedures which the assisted living facility shall follow in helping the resident find an appropriate placement;
 - 5. In a living unit in which more than one resident is the contracting party, the terms under which the contract may be modified in the event of one of the resident's discharge or death, including the provisions for termination of the contract and appropriate refunds.
 - F. Obligations of the facility and the resident as to:
 - 1. Arranging for or overseeing medical care; and
 - 2. Monitoring of the status of the resident.
 - G. The assisted living facility's formal internal grievance process which shall protect residents from reprisal by the facility or its employees.
 - H. An inventory of the resident's personal belongings, if the resident so desires.
- 63.907 The contract shall include, at a minimum, the following financial provisions:
- A. Party responsible for:
 - 1. Handling the finances of the resident;
 - 2. Purchasing or renting essential or desired equipment and supplies;
 - 3. Arranging and contracting for services not covered by the contract;
 - 4. Ascertaining the cost of and purchasing durable medical equipment; and
 - 5. Disposing of the resident's property upon discharge or death of the resident.
 - B. Rate structure and payment provisions including:
 - 1. All rates to be charged to the resident, including, but not limited to:
 - a. Service packages;
 - b. Fee for service rates; and
 - c. Other ancillary charges.
 - 2. Notification of the rate structure and the criteria to be used for imposing additional charges for the provision of additional services, if the resident's service and care needs change;
 - 3. Identification of the persons responsible for payment of all fees and charges and a clear indication of whether the person's responsibility is or is not limited to the extent of the resident's funds;
 - 4. A provision which provides at least 60 days notice of any rate increase, except if necessitated by a change in the resident's medical condition;
 - 5. Billing, payment, and credit policies, including the procedures that the assisted living facility will follow in the event the resident can no longer pay for services provided or for services or care needed by the resident; and
 - 6. A description of any prepaid fees or charges and the terms governing refund of those fees or charges in the event of a resident's discharge from the assisted living facility or termination of the contract.
- 63.908 The contract shall be amended by the parties to reflect any applicable increase or decrease in charges.
- 63.909 All notices to be provided pursuant to an assisted living contract shall be in writing and mailed or hand-

delivered to the resident.

63.910 No contract shall be signed before a full assessment of the resident has been completed and a service agreement has been executed. If a deposit is required prior to move-in, the deposit shall be fully refundable if the parties cannot agree on the services and fees upon completion of the assessment.

SECTION 63.10 RESIDENT ASSESSMENT

63.1001 Each assisted living facility shall use a Uniform Assessment Instrument (UAI) developed by the Division. The UAI shall be used in conducting all resident assessments.

63.1002 A resident seeking entrance shall have an initial UAI-based resident assessment completed by a registered nurse (RN) acting on behalf of the assisted living facility no more than 30 days prior to admission. In all cases, the assessment shall be completed prior to admission. Such assessment shall be reviewed by an RN within 30 days after admission and, if appropriate, revised. If the resident requires specialized medical, therapeutic, nursing services, or assistive technology, that component of the assessment must be performed by personnel qualified in that specialty area.

63.1003 Within 30 days prior to admission, a prospective resident shall have a medical evaluation completed by a physician.

63.1004 The resident assessment shall be completed in conjunction with the resident.

63.1005 The UAI, developed by the Department, shall be used to update the resident assessment. At a minimum, regular updates must occur 30 days after admission, annually and when there is a significant change in the resident's condition.

63.1006 If the needs of a resident exceed the care which the assisted living facility can provide and a waiver has not been requested, the facility shall assist the resident in making arrangements for an appropriate transfer within 30 days. While a transfer is pending, the assisted living facility shall coordinate the provision of services needed by the resident.

63.1007 The assisted living facility shall provide an instrument to assess interests, strengths, talents, skills and preferences of each resident within 30 days of admission to be used in activity planning.

SECTION 63.11 SERVICES

63.1101 The assisted living facility shall ensure that:

A. Three meals, snacks and prescribed food supplements are available during each 24-hour period, 7 days per week;

B. Meals and snacks are varied, palatable, and of sufficient quality and quantity to meet the daily nutritional needs of each resident with specific attention given to the special dietary needs of each resident;

C. Food service complies with the Delaware Food Code; and

D. A resident who chooses not to follow prescribed dietary recommendations shall be provided documented counseling on potential adverse outcomes.

63.1102 As part of the licensure approval and renewal process, an assisted living applicant or licensee shall submit at least a 4-week menu cycle with documentation by a dietician or nutritionist that the menus are nutritionally adequate. Thereafter, menus are to be written at least one week in advance and maintained on file, as served, for two months.

63.1103 The assisted living facility shall ensure that the resident's service agreement is being properly implemented.

63.1104 In accordance with the service agreement, the assisted living facility shall provide or ensure the provision of all necessary personal services, including all activities of daily living, and shall ensure that personal care supplies are available.

63.1105 The assisted living facility shall ensure that laundry and housekeeping services are offered and that all areas of the facility are maintained in a clean and orderly condition.

63.1106 In accordance with the service agreement, the assisted living facility shall be responsible for facilitating access to appropriate health care and social services for the resident.

63.1107 The assisted living facility shall assess each resident and provide or arrange appropriate opportunities for social interaction and leisure activities which promote the physical and mental well-being of each resident, including facilitating access to spiritual activities consistent with the preferences and background of the resident.

SECTION 63.12 SERVICE AGREEMENTS

63.1201 A service agreement based on the needs identified in the UAI shall be completed prior to or no later than the day of admission. The resident shall participate in the development of the agreement. The resident and the facility shall sign the agreement and each shall receive a copy of the signed agreement. All persons who sign the agreement must be able to comprehend and perform their obligations under the agreement.

63.1202 The service agreement or contract shall address the physical, medical, and psychosocial services that the resident requires as follows:

- A. Assistance with activities of daily living and instrumental activities of daily living;
- B. Services provided by licensed nurses;
- C. Food, nutrition, and hydration services;
- D. Environmental services including housekeeping, laundry, safety, trash removal;
- E. Psychosocial/emotional services including those related to memory impairment and other cognitive deficits;
- F. Banking, record keeping, and personal spending services;
- G. Transportation services;
- H. Individual living unit furnishings;
- I. Notification procedures when an incident occurs or there is a change in the health status of the resident;
- J. Assistive technology and durable medical equipment;
- K. Rehabilitation services;
- L. Qualified interpreters for people who have a hearing impairment or do not speak English; and
- M. Reasonable accommodations for persons with disabilities as defined by applicable state and federal law.

63.1203 The resident's personal attending physician(s) shall be identified in the service agreement by name, address, and telephone number.

63.1204 The facility shall be responsible for appropriate documentation in the service agreement for services provided or arranged by the facility.

63.1205 The service agreement shall be developed and followed for each resident consistent with that person's unique physical and psychosocial needs with recognition of his/her capabilities and preferences.

63.1206 The service agreement shall be reviewed when the needs of the resident have changed and, minimally, in conjunction with each UAI. Within 10 days of such assessment, the resident and the assisted living facility shall execute a revised service agreement, if indicated.

63.1207 The service agreement shall be based on the concepts of shared responsibility and resident choice. To participate fully in shared responsibility, residents shall be provided with clear and understandable information about the possible consequences of their decision-making. If a resident's preference or decision places the resident or others at risk or is likely to lead to adverse consequences, a managed/negotiated risk agreement section may be included in the service agreement.

63.1208 The following are criteria for a managed/ negotiated risk agreement:

- A. The risks are tolerable to all parties participating in the development of the managed/negotiated risk agreement;
- B. Mutually agreeable action is negotiated to provide the greatest amount of resident autonomy with the least amount of risk; and
- C. The resident living in the facility is capable of making choices and decisions and understanding consequences.

63.1209 If a managed/negotiated risk agreement is made a part of the service agreement, it shall:

- A. Clearly describe the problem, issue or service that is the subject of the managed/negotiated risk agreement;
- B. Describe the choices available to the resident as well as the risks and benefits associated with each choice, the assisted living facility's recommendations or desired outcome, and the resident's desired preference;
- C. Indicate the agreed-upon option;
- D. Describe the agreed upon responsibilities of the assisted living facility, the resident, and any third parties;
- E. Become a part of the service agreement, be signed separately by the resident, the assisted living facility, and any third party with obligations under the managed/ negotiated risk agreement that the third party is able to fully comprehend and perform; and
- F. Include a time frame for review.

63.1210 The assisted living facility shall have sufficient staff to meet its responsibilities under the managed/ negotiated risk agreement.

63.1211 The assisted living facility shall not use managed/negotiated risk agreements to provide care to residents with needs beyond the capability of the facility. A managed/negotiated risk agreement shall not be used to supersede

any requirements of these regulations.

63.1212 The assisted living facility shall make no attempt to use the managed/negotiated risk portion of the service agreement to abridge a resident's rights or to avoid liability for harm caused to a resident by the negligence of the assisted living facility and any such abridgement or disclaimer shall be void.

SECTION 63.13 RESIDENT RIGHTS

63.1301 Assisted living facilities are required by 16 **Del.C.** Chapter 11, Subchapter II, to comply with the provisions of the Rights of Patients covered therein.

63.1302 Each resident has the right of privacy in his/her room, including a door that locks, consistent with the safety needs of the resident.

SECTION 63.14 QUALITY ASSURANCE

63.1401 The assisted living facility shall develop, implement, and adhere to a documented, ongoing quality assurance program that includes an internal monitoring process that tracks performance and measures resident satisfaction.

63.1402 On at least a semi-annual basis, the assisted living facility shall survey each resident regarding his/her satisfaction with services provided.

A. The assisted living facility shall retain all surveys for at least two years which shall be reviewed during inspection.

B. The assisted living facility shall maintain documentation for at least one year which addresses what actions were taken as a result of the surveys.

SECTION 63.15 STAFFING

63.1501 As used herein "staff" includes permanent employees of the assisted living facility and independent contractors, including "temps."

63.1502 A staff of persons sufficient in number and adequately trained, certified or licensed to meet the requirements of the residents shall be employed and shall comply with applicable state laws and regulations.

63.1503 All direct care staff shall be familiar with the service agreement for each resident for whom they provide care.

63.1504 Every assisted living facility shall have a Director. Facilities licensed for 25 beds or more shall have a full-time Nursing Home Administrator. Facilities licensed for 5 through 24 beds shall have a part-time Nursing Home Administrator on-site and on-duty at least 20 hours a week. If the assisted living facility is part of a continuing care retirement community (CCRC) or part of a campus under the same ownership, the CCRC or campus may operate under one licensed Nursing Home Administrator.

63.1505 The Nursing Home Administrator shall comply with the provisions of 24 **Del.C.**, Chapter 52, and the Board's Rules and Regulations.

63.1506 The Director/Nursing Home Administrator shall have overall responsibility for managing the assisted living facility such that all requirements of state law and regulations are met.

63.1507 The Director of a facility for 4 beds or fewer shall meet one of the following criteria:

- A. A baccalaureate degree in a health or social services field or business administration; or
- B. An associates degree in a health or social services field or business administration and at least 2 years of full-time equivalent work experience in these disciplines; or
- C. An RN with a combined total of 4 years full-time equivalent education and related work experience; or
- D. At least 4 years full-time equivalent work experience as an LPN, or 5 years full-time equivalent work experience in a health or social services field or business administration.

63.1508 The Director of a Facility for 4 beds or fewer shall be on-site at least 8 hours a week.

63.1509 Each facility for 4 beds or fewer shall have a full-time, on-site house manager who shall at a minimum:

- A. Possess a high school diploma or its equivalent;
- B. Be certified as a CNA with at least three years experience providing care in a health care setting;
- C. Complete an orientation program in accordance with the CNA regulations; and
- D. Receive, at a minimum, 12 hours of regular in-service education annually, which may include but not be limited to the topics listed below:
 - 1. The health and psychosocial needs of the population being served;
 - 2. The resident assessment process;

3. Use of service agreements;
4. Cuing, coaching, and monitoring residents who self-administer medications, with or without assistance;
5. Providing assistance with ambulation, personal hygiene, dressing, toileting, and feeding;
6. 16 **Del.C.**, Chapter 11, pertaining to resident's rights; reporting of abuse, neglect, mistreatment, and financial exploitation; and the Ombudsman Program;
7. Fire and life safety, and emergency disaster plans;
8. Infection control, including Standard Precautions;
9. Basic food safety;
10. Basic first aid, CPR, and the Heimlich Maneuver; and
11. Hospice services.

63.1510 Assisted living facilities administering therapies and/or treatments shall have staff adequate in number and appropriately qualified and/or licensed.

63.1511 Every assisted living facility shall have a Director of Nursing who is a registered nurse. Facilities licensed for 25 assisted living beds or more shall have a full-time Director of Nursing. Facilities licensed for 5 through 24 assisted living beds shall have a part-time Director of Nursing on-site and on-duty at least 20 hours a week. The nursing director of a facility for 4 assisted living beds or fewer shall be on-site at least 8 hours a week.

63.1512 The Director of Nursing shall comply with the provisions of 24 **Del.C.** Ch. 19 and the rules and regulations of the Board of Nursing.

63.1513 The Director of Nursing shall have overall responsibility for the coordination, supervision and provision of the nursing department /services.

63.1514 Assisted living facility resident assistants shall, at a minimum:

- A. Be at least 18 years old;
- B. Participate in a facility-specific orientation program that covers the following topics:
 1. Fire and life safety, and emergency disaster plans;
 2. Infection control, including Standard Precautions;
 3. Basic food safety;
 4. Basic first aid and the Heimlich Maneuver;
 5. Job responsibilities;
 6. The health and psychosocial needs of the population being served;
 7. The resident assessment process; and
 8. The use of service agreements;
 9. 16 **Del.C.**, Chapter 11, pertaining to residents' rights; reporting of abuse, neglect, mistreatment, and financial exploitation; and the Ombudsman Program;
 10. Hospice services.
- C. Receive, at a minimum, 12 hours of regular in-service education annually which may include but not be limited to the topics listed in 63.1514 B;
- D. Receive training to competently assist in activities of daily living or provide documentation of such training, and
- E. Complete a Delaware Board of Nursing-approved AWSAM training course if assisting with self-administration of medications.

63.1515 The assisted living facility shall have a staffing plan which shall specify supervisory responsibilities, including the person responsible in the Assisted Living Director's absence.

63.1516 The assisted living facility shall maintain staffing records which document what personnel were on duty as well as specific hours worked for each day.

63.1517 The assisted living facility shall maintain a copy of each employee's signature and handwritten initials.

63.1518 The assisted living facility shall maintain records of each employee's regular in-service education hours.

63.1519 The assisted living facility shall provide orientation training to all new staff.

63.1520 Temporary agency staff placed in a facility in which they have not worked within the past 6 months shall undergo an orientation prior to beginning their first shift. The orientation shall cover the following topics:

- A. Tour of the facility;
- B. Fire and disaster plans;
- C. Emergency equipment and supplies;
- D. Communication and documentation requirements of the facility;
- E. Process for reporting emergencies and change of condition; and
- F. Review of current assigned resident issues/ needs.

63.1521 All personnel records for permanent employees, including employment applications, shall be maintained for a minimum of five years consistent with the assisted living facility policies and applicable state laws.

63.1522 At a minimum, every assisted living facility shall have an awake staff person on-site 24 hours per day who is qualified to administer or assist with self-administration of medication (“AWSAM”) and who has knowledge of emergency procedures, basic first aid, CPR, and the Heimlich Maneuver.

63.1523 Written policies and procedures shall be required and adhered to for any assisted living facility utilizing volunteers.

SECTION 63.16 ENVIRONMENT AND PHYSICAL PLANT

63.1601 Each assisted living facility shall comply with applicable federal, state and local laws including:

- A. Rehabilitation Act, Section 504;
- B. Fair Housing Act as amended; and
- C. Americans with Disabilities Act.

63.1602 Assisted living facilities shall:

- A. Be in good repair;
- B. Be clean;
- C. Have a hazard-free environment; and
- D. Have an effective pest control program.

63.1603 Heating and cooling systems in common areas shall be maintained at a temperature between 71° F and 81° F. A resident with an individual temperature-controlled residential room or unit may heat and cool to provide individual comfort.

63.1604 Common areas shall be lighted to assure resident safety.

63.1605 For all new construction and conversions of assisted living facilities with more than 10 beds, there shall be at least 100 square feet of floor space, excluding alcoves, closets, and bathroom, for each resident in a private bedroom and at least 80 square feet of floor space for each resident sharing a bedroom.

- A. Sharing of a bedroom shall be limited to 2 residents;
- B. Each facility shall have locked storage available for the resident’s valuables, in accordance with the facility’s policies;
- C. Bedrooms and all bathrooms used by residents in assisted living facilities, except in specialized care units for memory impairment, shall be equipped with an intercom or other mechanical means of communication for resident emergencies. For specialized care units for memory impairment, staff must be equipped to communicate resident emergencies immediately.

63.1606 Resident kitchens shall be available to residents either in their individual living unit or in an area readily accessible to each resident. Residents shall have access to a microwave or stove/conventional oven, refrigerator, and sink. The assisted living facility shall establish and adhere to policies and procedures to ensure that common kitchens are used and maintained in such a way as to provide:

- A. A clean and sanitary environment;
- B. Safe storage of food; and
- C. A means to enable hand washing and sanitizing of dishes, utensils and food preparation equipment.

63.1607 Bathroom facilities shall be available to residents either in their individual living units or in an area readily accessible to each resident. There shall be at least 1 working toilet, sink, and tub/shower for every 4 residents.

63.1608 Hot water at resident bathing and hand-washing facilities shall not exceed 120 degrees Fahrenheit.

[63.1609 An assisted living facility shall have a functioning emergency generator adequate to supply power in the event that the normal electrical supply is interrupted. The required emergency generating system shall conform to NFPA 99 Life Safety Code and NFPA 101 Life Safety Code.

63.1610 The emergency generator shall supply power for the following:

- A. Illumination of means of egress in stairs, facility vestibules, aisles, corridors and ramps leading to an exit. Illumination shall not be less than one foot candle.**
- B. Illumination of exit signs and exit directional signs. Illumination shall not be less than one foot candle.**
- C. Fire detection, fire alarm and fire extinguishing systems.**
- D. Communication systems including telephones, public address system and nurse call or resident intercom system.**
- E. Lighting in dining and recreation areas to provide illumination to exit ways. Illumination shall**

not be less than 5 foot candles.

F. Elevator cab lighting, control, communication and signal systems including the capacity to operate the elevator to release passengers trapped between floors.

G. Task illumination and at least one electrical receptacle in each area listed below. The cover plate on such receptacles shall have a distinctive color or marking.

1. Medication dispensing areas.

2. Direct care charting areas.

3. Resident rooms.

4. Kitchen.

H. Refrigeration units, kitchen hood and/or exhaust systems.

I. Sump pump.

J. Heating/air conditioning, sufficient to prevent resident distress, in corridors, common areas and any selected room(s) designated for congregate use during a power outage.]

SECTION 63.17 FIRE SAFETY AND OTHER EMERGENCY PLANS

63.1701 The assisted living facility shall comply with all applicable state and local fire and building codes. All applications for license or renewal of license shall include a letter certifying compliance by the Fire Marshal having jurisdiction. Notification by the Fire Marshal of non-compliance with the Rules and Regulations of the State Fire Prevention Commission shall be grounds for enforcement remedies in 16 Del.C., Chapter 11, Subchapter I, Licensing By The State.

63.1702 The assisted living facility shall:

A. Develop and implement through staff training and drills a plan for use in fire and other emergencies, which clearly outlines the procedures to be followed and the responsibilities designated to staff.

63.1703 Develop a plan for relocation and/or evacuation and continuous provision of services to residents in the event of permanent or temporary closure of the assisted living facility. The evacuation plan shall be approved by the Fire Marshal having jurisdiction and shall include the evacuation route, which shall be conspicuously posted on each floor and in each unit.

63.1704 The assisted living facility shall promote staff knowledge of fire and other emergency safety by:

A. Orienting staff to the emergency plan and to individual responsibilities within 24 hours of the commencement of job duties;

B. Documenting completion of orientation in staff member's personnel file with employee's signature;

C. Conducting facility fire drills in accordance with State of Delaware Fire Prevention Regulations;

D. Conducting other facility emergency drills or training sessions on all shifts at least annually; and

E. Maintaining records for two years of facility fire and other emergency drills/training sessions.

63.1705 The assisted living facility shall promote resident fire and other emergency safety by:

A. Orienting residents to the emergency plan within 24 hours of their admission into the assisted living facility;

B. Documenting the orientation such that it is signed and dated by the resident; and

C. Maintaining records identifying residents needing assistance for evacuation.

SECTION 63.18 RECORDS AND REPORTS

63.1801 The assisted living facility shall be responsible for maintaining appropriate records for each resident. These records shall document the implementation of the service agreement for each resident.

63.1802 Records shall be available, along with the equipment to read them if electronically maintained, at all times to legally authorized persons; otherwise such records shall be held confidential.

63.1803 The assisted living facility resident clinical records shall be retained for a minimum of 5 years following discharge before being destroyed.

63.1804 In cases in which facilities have created the option for an individual's record to be maintained by computer, rather than hard copy, electronic signatures shall be acceptable. In cases when such attestation is done on computer records, safeguards to prevent unauthorized access and reconstruction of information must be in place. The following is an example of how such a system may be set up:

A. There is a written policy, at the assisted living facility, describing the attestation policy(ies) in force at the facility;

B. The computer has built-in safeguards to minimize the possibility of fraud;

C. Each person responsible for an attestation has an individualized identifier;

D. The date and time is recorded from the computer's internal clock at the time of entry;

E. An entry is not to be changed after it has been recorded; and

F. The computer program controls what sections/ areas any individual can access/enter data based on the individual's personal identifier.

63.1805 Incident reports, with adequate documentation, shall be completed for each incident. Records of incident reports shall be retained in facility files for the following:

A. All reportable incidents.

B. Falls without injury and falls with injuries that do not require transfer to an acute care facility or do not require reassessment of the resident.

C. Errors or omissions in treatment or medication.

D. Injuries of unknown source.

E. Lost items, in accordance with facility policy, which are not subject to financial exploitation. 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 and any accused persons; 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.

~~63.1806 Incident reports shall be kept on file in the facility.~~ Reportable incidents shall be ~~communicated reported~~-immediately, which shall be within 8 hours of the occurrence of the incident, to the Division of Long Term Care Residents Protection, 3 Mill Road, Suite 308, Wilmington, DE 19806; telephone number: 1-877-453-0012; fax number: 1-877-264-8516. The immediate reporting of reportable incidents shall be by oral communication, for which a fax may be substituted, followed within 48 hours by a written report on a form provided by the Division.

63.1807 Reportable incidents include:

A. Abuse as defined in 16 Del.C. §1131.

1. Physical abuse.

a. Staff to resident with or without injury.

b. Resident to resident with or without injury.

c. Other (e.g., visitor, relative) to resident with or without injury.

2. Sexual abuse.

a. Staff to resident sexual acts.

b. Resident to resident non-consensual sexual acts.

c. Other (e.g., visitor, relative) to resident non-consensual sexual acts.

3. Emotional abuse.

a. Staff to resident.

b. Resident to resident.

c. Other (e.g., visitor, relative) to resident.

B. Neglect as defined in 16 Del.C. §1131.

C. Mistreatment as defined in 16 Del.C. §1131.

D. Financial exploitation as defined in 16 Del.C. §1131.

E. Resident elopement.

1. Any circumstance in which a resident's whereabouts are unknown to staff and the resident suffers harm.

2. Any circumstance in which a cognitively impaired resident, whose whereabouts are unknown to staff, exits the facility.

3. Any circumstance in which a resident cannot be found inside or outside a facility and the police are summoned.

F. Death of a resident in a facility or within 5 days of transfer to an acute care facility.

G. Significant injuries.

1. Injury from an incident of unknown source in which the initial investigation concludes that there is reasonable suspicion that the injury was caused by abuse, neglect or mistreatment.

2. Injury from a fall which results in transfer to an acute care facility for treatment or evaluation or which requires periodic reassessment of the resident's clinical status by facility professional staff for up to 48 hours.

3. Injury sustained while a resident is physically restrained.

4. Injury sustained by a resident dependent on staff for toileting, mobility, transfer and/or bathing.

5. Significant error or omission in medication/treatment, including drug diversion, which causes the resident discomfort, jeopardizes the resident's health and safety or requires extensive

monitoring for up to 48 hours.

6. A burn greater than first degree.
7. Choking resulting in transfer to an acute care facility.
8. Areas of contusions or lacerations which may be attributable to abuse or neglect.
9. Serious unusual and/or life-threatening injury.
- H. Attempted suicide.
- I. Poisoning.
- J. Epidemic outbreak or quarantine.
- K. Fire within a facility due to any cause.
- L. Utility interruption lasting more than 8 hours in one or more major service including electricity, water supply, plumbing, heating or air conditioning, fire alarm, sprinkler system or telephone system.
- M. Structural damage or unsafe structural conditions.
 1. Structural damage to a facility due to natural disasters such as hurricanes, tornadoes, flooding or earthquakes.
 2. Water damage which impacts resident health, safety or comfort.

SECTION 63.19 WAIVERS AND SEVERABILITY

63.1901 Waivers may be granted by the Division for good cause.

63.1902 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.

See 6 DE Reg. 525 (10/1/02)

APPENDIX A Notifiable Diseases

Acquired Immune Deficiency Syndrome (S)
Anthrax (T)
Botulism (T)
Brucellosis
Campylobacteriosis
Chancroid (S)
Chlamydia trachomatis infections (S) g
Cholera
Cryptosporidiosis
Cyclosporidiosis
Diphtheria (T)
E. Coli 0157:H7 infection (T)
Encephalitis
Ehrlichiosis
Foodborne Disease Outbreaks (T)
Giardiasis
Gonococcal infections (S)
Granuloma Inguinale (S)
Hansen's Disease (Leprosy)
Hantavirus infection (T)
Hemolytic uremic syndrome (HUS)
Hepatitis A (T)
Hepatitis B (S)
Hepatitis C & unspecified
Herpes (congenital) (S)
Herpes (genital) (N)
Histoplasmosis
Human Immunodeficiency Virus (HIV) (N)
Human papillomavirus (genital warts) (N)
Influenza (N)
Lead Poisoning

Legionnaires Disease
 Leptospirosis
 Lyme Disease
 Lymphogranuloma Venereum (S)
 Malaria
 Measles (T)
 Meningitis (all types other than meningoccal)
 Meningococcal infections (all types) (T)
 Mumps (T)
 Pelvic Inflammatory Disease (resulting from gonococcal
 and/or chlamydial infections) (S)
 Pertussis (T)
 Plague (T)
 Poliomyelitis (T)
 Psittacosis
 Rabies (man, animal) (T)
 Reye's Syndrome
 Rocky Mountain Spotted Fever
 Rubella (T)
 Rubella (congenital)(T)
 Salmonellosis
 Shigellosis
 Smallpox (T)
 Streptococcal disease (invasive group A)
 Streptococcal toxic shock syndrome (STSS)
 Syphilis (S)
 Syphilis (congenital) (T)
 Tetanus
 Toxic Shock Syndrome
 Trichinosis
 Tuberculosis
 Tularemia
 Typhoid Fever (T)
 Vaccine Adverse Reactions
 Varicella
 Waterborne Disease Outbreaks (T)
 Yellow Fever (T)

Also, any unusual disease and adverse reaction to vaccine
 County Health Offices:

New Castle County	995-8632
Kent County	739-5305
Sussex County	856-5355

(T) report by rapid means

(N) report in number only when so requested

For all diseases not marked by (T) or (N):

(S) – sexually transmitted disease, report required in 1 day

Others – report required in 2 days

See 6 DE Reg. 525 (10/1/02)

8 DE Reg. 85 (7/1/04)