

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF HEALTH CARE QUALITY

Statutory Authority: 16 Delaware Code, Section 1119C (16 Del.C. §1119C)
16 DE Admin. Code 3225

FINAL

ORDER

3225 Assisted Living Facilities

Nature of The Proceedings

Delaware Health and Social Services ("DHSS") initiated proceedings to adopt the State of Delaware Regulations Governing Assisted Living Facilities. The DHSS proceedings to adopt regulations were initiated pursuant to 29 Delaware Code Chapter 101 and authority as prescribed by 16 Delaware Code Section 1119C.

On June 1, 2020, DHSS published in the *Delaware Register of Regulations* its notice of emergency regulations pursuant to 16 Del.C. §1119C and 29 Del.C. §10119. On October 1, 2020 (Volume 24, Issue 4), DHSS published in the *Delaware Register of Regulations* its notice of both emergency and proposed regulations, pursuant to 16 Del.C. §1119C and 29 Del.C. §10119 and 29 Del.C. §10115, respectively. It requested that written materials and suggestions from the public concerning the proposed regulations be delivered to DHSS by November 2, 2020, after which time DHSS would review information, factual evidence and public comment to the said proposed regulations.

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

Summary of Proposal

Effective December 1, 2020, DHSS/Division of Health Care Quality (DHCQ) is publishing the final regulations governing Assisted Living Facilities.

Background

Rapid and widespread transmission of COVID-19 is of significant concern within congregate settings, particularly within nursing facilities, assisted living facilities, rest (residential) facilities, and intermediate care facilities for persons with intellectual disabilities.

Because asymptomatic or presymptomatic residents and staff might play an important role in transmission in facilities, additional prevention measures merit consideration, including using testing to guide the use of transmission-based precautions, isolation, and cohorting strategies. The ability to test large numbers of residents and staff may significantly decrease transmission of COVID-19 within facilities.

Statutory Authority

16 Del.C. §1119C

Purpose

The purpose of the amendment was to update the regulatory language to include the emergency regulations published on June 1, 2020. This language expands definitions, documentation, emergency preparedness, and testing requirements for assisted living facilities.

Fiscal Impact

N/A

SUMMARY OF EVIDENCE

STATE OF DELAWARE REGULATIONS GOVERNING ASSISTED LIVING FACILITIES

In accordance with Delaware Law, public notices regarding proposed Department of Health and Social Services (DHSS) Regulations Governing Assisted Living Facilities were published in the *Delaware Register of Regulations*. Written comments were received on the proposed regulations during the public comment period (October 1, 2020 through November 2, 2020).

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

Ann C. Fisher, Chairperson Governor's Advisory Council for Exceptional Citizens

Comment: The Governor's Advisory Council for Exceptional Citizens (GACEC) has reviewed the Delaware Health and Social Services (DHSS)/Division of Health Care Quality (DHCQ) Emergency and Proposed regulations governing testing for COVID-19 in nursing homes, immediate care nursing facilities, assisted living facilities and rest (residential) facilities. Council understands that the emergency regulations (304, 306 and 308) extend the mandatory testing and other protocols for each type of facility for 60 days, based on the Governor's Emergency Orders. The proposed regulations (315, 317 and 320) are identical to the emergency regulations and allow the public an opportunity to provide comments. Council would like to share the following observations and will group our comments as they all pertain to each of the facility types noted.

First, section 6.11.1.1 [9.8.1.1] suggests but does not compel resident testing upon identification of another resident with symptoms consistent with COVID-19 or if staff have tested positive. The Division of Public Health (DPH) could mandate testing of residents. Shouldn't residents be tested if staff are suspected of COVID rather than waiting for positive test results before testing?

Response: Thank you for your comment. Staff with symptoms or signs of COVID-19 must be tested for COVID-19 and are expected to be restricted from the facility pending the results of COVID-19 testing. Residents who have signs or symptoms of COVID-19 should also be tested for COVID-19. While test results are pending, residents with signs or symptoms should be placed on transmission-based precautions (TBP) in accordance with Centers for Disease Control and Prevention guidance. Upon identification of a single new case of COVID-19 infection in any staff, all residents should be tested per the Centers for Disease Control and Prevention and the Division of Public Health guidance. Per 16 Delaware Code §1121, each resident has the right to refuse medication or treatment. The skilled and intermediate care nursing facility must offer COVID-19 testing and explain the consequences of not testing; however, the facility cannot force a resident to be tested for COVID-19.

Comment: Second, section 6.11.1.2 [9.8.1.2] states that all other testing should be consistent with DPH guidance **during the emergency**. Council feels this should be mandatory language beyond the pandemic. Is it up to the facility to decide whether to follow DPH guidance? Even when COVID-19 is no longer at pandemic level it will still be a dangerous infectious disease, particularly for residents of these types of facilities. Therefore, it should still be a requirement to test for positive cases until the Centers for Disease Control (CDC) and state health department indicate that there is no remaining threat of transmission.

Response: Thank you for your comment. The Department of Health and Social Services will address this issue in a future revision.

Comment: Third, section 6.11.1.3 [9.8.1.3] states that all testing must be documented in the medical record and section 6.11.1.4 [9.8.1.4] states that all resident results must be reported to DPH. Likewise, section 6.11.2.1 [9.8.2.1] states that all staff, vendors and volunteers must be tested within two weeks of the effective date of the regulation. This language is confusing. Are the facilities being asked to do a new run of testing or keep going with the existing protocol?

Fourth, section 6.11.2.2 [9.8.2.2] states that all new staff, vendors and volunteers who cannot provide proof of a previous positive testing must be tested prior to their start date. There is no evidence regarding the duration of any immunity that previous infection may create. There is no timeframe for when any prior positive test might have occurred. Therefore, any new staff, vendor or volunteer needs to have a recent (within several days) negative test prior to accessing any facility.

Response: Thank you for your comment. All long term care facilities are required to document all test results in the resident medical record. In addition, all test results must be reported to the Division of Public Health. Long term care facilities have been completing COVID-19 testing in accordance with the Division of Public Health guidance since June 2020. Due to the changing guidance regarding the testing of persons that previously tested positive for COVID-19, the regulations will be clarified as follows:

6.11.2.1 [9.8.2.1] remove

6.11.2.2 [9.8.2.2] Prior to their start date, all new staff, vendors and volunteers must be tested in accordance with the Delaware Division of Public Health Guidance.

Comment: Fifth, section 6.11.2.3 [9.8.2.3] states that all staff, vendors and volunteers must be retested consistent with DPH guidelines for the duration of the public health emergency. Council queries what happens after the public health emergency? Should facilities be screening staff, vendors and volunteers for COVID-19 in some fashion on an ongoing basis until the CDC and DPH indicate there is no remaining threat of transmission?

Response: Thank you for your comment. The Department of Health and Social Services will address the testing of staff, vendors and volunteers after the public health emergency in a future revision.

Comment: Sixth, section 6.11.2.5 [9.8.2.5] is confusing. It states that facilities must follow the recommendations of CDC and DPH regarding provision of care and services for residents by staff, vendor or volunteer found to be positive for COVID-19. Is this suggesting that facilities can allow staff and others who test positive to continue to care for residents consistent with CDC guidelines? Council understands there was some discussion early in the pandemic about allowing

asymptomatic COVID-19 positive staff to continue to work because of shortages. Council would not endorse this practice and asks for clarification on the meaning of this section.

Response: Thank you for your comment. This regulation requires skilled and intermediate care nursing facilities to follow the recommendations and guidance from the Centers for Disease Control and Prevention and the Delaware Division of Public Health, both of which are based on nationally recognized standards of practice.

Comment: Seventh, section 6.11.2.6 [9.8.2.6] discusses a series of provisions requiring facilities to amend communicable diseases policies and procedures regarding work exclusion and return to work protocols, staff refusals to test, staff refusals to consent to release of test results, procedures to obtain staff authorizations for obtaining test results, and plans to address staffing shortages and facility demands. Council notes that this particular regulation provides no particulars or guidance about the parameters or requirements for these policies. For example, would it not make sense to indicate that staff that refuse testing should be suspended from work until they agree and are tested? Without having some degree of specificity and guidelines, this requirement is essentially meaningless. Can facilities each make up their own rules for when a positive employee can return to work?

Response: Thank you for your comment. Facilities must base policies and procedures on recognized standards of practice. Per regulation 6.11.2.5 [9.8.2.5], facilities must follow the recommendations of the Centers for Disease Control and Prevention and the Delaware Division of Public Health.

Comment: Eighth, section 8.3 [18.3] adds the requirement that facilities include plans to address staff shortages and facility demands as part of their Emergency Preparedness Plan. Council appreciates this requirement.

Response: Thank you for your comment.

Terri Hancharick, Chairperson, State Council for Persons with Disabilities (SCPD)

Comment: The State Council for Persons with Disabilities (SCPD) has reviewed the Division of Health Care Quality's (DHCQ's) emergency and proposed regulations regarding COVID-19 testing at Skilled and Intermediate Care Nursing Facilities, Assisted Living Facilities and Rest (Residential) Facilities. The emergency regulations were published as 24 DE Reg. 304, 306 and 308, and the proposed regulations were published at 315, 317 and 320 in the October 1, 2020 issue of the Register of Regulations. The emergency regulations appear to renew policies for mandatory testing and other protocols for each type of facility and the proposed regulations offer an opportunity for public input. SCPD has the following observations.

6.11.1.1 [9.8.1.1] suggests, but does not compel, resident testing upon identification of another resident with symptoms consistent with COVID or if staff have tested positive. SCPD believes DHCQ could mandate testing of residents and strongly recommends such testing. In addition, shouldn't they test residents if staff are suspected of COVID and not wait for a positive test?

Response: Thank you for your comments. Staff with symptoms or signs of COVID-19 must be tested for COVID-19 and are expected to be restricted from the facility pending the results of COVID-19 testing. Residents who have signs or symptoms of COVID-19 should also be tested for COVID-19. While test results are pending, residents with signs or symptoms should be placed on transmission-based precautions (TBP) in accordance with Centers for Disease Control and Prevention guidance. Upon identification of a single new case of COVID-19 infection in any staff, all residents should be tested per the Centers for Disease Control and Prevention and the Division of Public Health guidance. Per 16 Delaware Code, §1121, each resident has the right to refuse medication or treatment. The skilled and intermediate care nursing facility must offer COVID-19 testing and explain the consequences of not testing; however, the facility cannot force a resident to be tested for COVID-19.

Comment: 6.11.1.2 [9.8.1.2] states that all other testing should be consistent with DPH guidance during the emergency. SCPD strongly recommends that this be mandatory language? Is it up to the facility to decide whether to follow DPH guidance? Shouldn't the requirement to test if there are positive cases continue even if the public health emergency is no longer in effect? It is absolutely conceivable that coronavirus will be in existence after the emergency has ended.

Response: Thank you for your comment. The testing is mandatory and Department of Health and Social Services will address the issue of the timeframe in a future revision.

Comment: 6.11.1.3 [9.8.1.3] requires that all testing be documented in the medical record.

6.11.1.4 [9.8.1.4] requires that all resident results be reported to DPH.

6.11.2.1 [9.8.2.1] requires all staff, vendors and volunteers be tested within two weeks of the effective date of the regulation. SCPD believes it makes no sense to keep this language. Are they asking for the facilities to do a new run of testing or keep going with the existing protocol?

6.11.2.2 [9.8.2.2] requires all new staff, vendors and volunteers who cannot provide proof of a previous positive testing be tested prior to their start date. There is no evidence regarding the duration of any immunity that previous infection may create. There is no timeframe for when any prior positive test might have occurred. Therefore, any new staff, vendor or volunteer needs to have a recent (within several days) negative test prior to accessing any facility.

Response: Thank you for your comment. All long term care facilities are required to document all test results in the resident medical record. In addition, all test results must be reported to the Division of Public Health. Long term care facilities have been completing COVID-19 testing in accordance with the Division of Public Health guidance since June 2020. Due to the changing guidance regarding the testing of persons that previously tested positive for COVID-19, the regulations will be clarified as follows:

6.11.2.1 [9.8.2.1] remove

6.11.2.2 [9.8.2.2] Prior to their start date, all new staff, vendors and volunteers must be tested in accordance with the Delaware Division of Public Health Guidance.

Comment: 6.11.2.3 [9.8.2.3] requires all staff, vendors and volunteers be retested consistent with DPH guidelines for the duration of the public health emergency. Again, what about after the public health emergency? Facilities should be screening staff, vendors and volunteers for COVID-19 in some fashion on an ongoing basis?

Response: Thank you for your comment. The Department of Health and Social Services will address the testing of staff, vendors and volunteers after the public health emergency in a future revision.

Comment: 6.11.2.4 [9.8.2.4] requires that facilities must report all staff, vendor and volunteer testing results to DPH.

6.11.2.5 [9.8.2.5] requires that facilities follow recommendations of CDC and DPH regarding provision of care and services for residents by staff vendor or volunteer found to be positive for COVID-19. SCPD is not entirely sure what this means. Is it suggesting that facilities can allow staff and others who test positive to continue to care for residents consistent with CDC guidelines? There was some discussion early in the pandemic about allowing asymptomatic COVID positive staff to continue to work because of shortages. This section may be more to do with how long staff need to stay off work or get negative testing, although that appears to be addressed in Section 6.11.2.6 [9.8.2.6]. SCPD respectfully requests clarification on this issue.

Response: Thank you for your comment. This regulation requires skilled and intermediate care nursing facilities to follow the recommendations and guidance from the Centers for Disease Control and Prevention and the Delaware Division of Public Health, both of which are based on nationally recognized standards of practice.

Comment: 6.11.2.6 [9.8.2.6] includes provisions requiring facilities to amend communicable diseases policies and procedures regarding work exclusion and return to work protocols, staff refusals to test, staff refusals to consent to release of test results, procedures to obtain staff authorizations for obtaining test results, and plans to address staffing shortages and facility demands. SCPD recommends that this section of the regulation provides particulars or guidance about the parameters or requirements for these policies – it currently does not provide such information. For example, wouldn't it make sense to indicate that staff that refuse testing should be suspended from work until they get tested? Without having some degree of specificity and guidelines, this requirement is essentially meaningless. Can facilities each make up their own rules for when a positive employee can return to work?

Response: Thank you for your comment. Facilities must base policies and procedures on recognized standards of practice. Per regulation 6.11.2.5 [9.8.2.5], facilities must follow the recommendations of the Centers for Disease Control and Prevention and the Delaware Division of Public Health.

Comment: 12.8.3 [18.3.1] adds the requirement that facilities include plans to address staff shortages and facility demands as part of their Emergency Preparedness Plan. SCPD endorses this requirement.

SCPD strongly encourages DHCQ to implement the aforementioned recommendations. Regarding outbreaks at long-term care facilities, a Delaware Online October 30th article reports that, "(of) the state's 704 coronavirus-related deaths, 409 (58%) were residents in such facilities." <https://www.delawareonline.com/story/news/coronavirus-in-delaware/2020/10/30/delawares-covid-19-death-count-tops-700-latest-state-update-coronavirus-in-delaware/6089390002/>

Delaware continues to be far worse than the national average in protecting residents in long-term care facilities. An October 30th New York Times article reported that (s)ince the outbreak, the deaths of residents of long-term care facilities swelled to account for almost 40 percent of the country's 229,600 coronavirus deaths. <https://gcc02.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.nytimes.com%2F2020%2F10%2F30%2Fus%2Fnursing-homes-isolation-virus.html&data=04%7C01%7CKyle.Hodges%40delaware.gov%7Cfec60f17a67745e79ccf08d87daa5cee%7C8c09e56951c54deeabb28b99c32a4396%7C0%7C0%7C637397517964119292%7CUnknown%7CTWFpbGZsb3d8eyJWlloiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6IjEkaWwWwLJXVCi6Mn0%3D%7C1000&sdata=9ZdWGzDBMZWL%2FuQuwMdSF2%2FGIB%2FMSahxfNqY2SskLw%3D&reserved=0>

Delaware, in the short-term, must implement mandatory standards to reverse this trend. In addition, it has become evident that living in congregate living facilities is literally dangerous and far more unsafe than living in the community. Therefore, as SCPD has long advocated, more funding is needed now and in the future for home and community-based services.

Thank you for your consideration and please contact the SCPD if you have any questions regarding our observations

or recommendations on the proposed regulations.

Response: Thank you for your comments.

Findings of Fact:

Non-substantive changes were made to the regulations based on the comments received and detailed in the "Summary of Evidence." The Department finds that the proposed regulations, as set forth in the attached copy with additions pursuant to 29 Delaware Code Section 10118(c), should be adopted in the best interest of the general public of the State of Delaware.

THEREFORE, IT IS ORDERED, that the proposed State of Delaware Regulations Governing Assisted Living Facilities is adopted and shall become effective December 11, 2020, after publication of the final regulation in the *Delaware Register of Regulations*.

11/16/2020

Date

Molly K. Magarik, Secretary, DHSS

3225 Assisted Living Facilities

1.0 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.

2.0 Authority and Applicability

These regulations are promulgated in accordance with 16 **Del.C.** Ch. 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.

3.0 Glossary of Terms

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

"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.

"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.

"Assisted Living Facility" - A licensed entity that provides the services described in **Assisted Living**.

"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.

"Assistance with Self-Administration of Medication" ("AWSAM") - Assistance 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. Assistance 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.

"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.

"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.

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

“Department” - Department of Health and Social Services.

“Division” - Division of Long Term Care Residents Protection.

“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.

“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.

“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.

“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 19.5 of these regulations. (Also see Reportable Incident, 19.6 and 19.7)

“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.

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

“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.

“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; 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.

“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.

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

“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 as those terms are defined in 16 Del.C. §1131. Reportable incident also includes an occurrence or event listed in Sections 19.6 and 19.7 of these regulations. (Also see Incident, 19.5.)

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

“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 3.0.

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

“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.

“Secretary” - Secretary of the Department of Health and Social Services.

“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.

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

“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.

“Significant Medication Error” – means one which causes the resident discomfort or jeopardizes his or her health or safety.

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

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

“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.

“Vendor” – Any individual who is not employed by the facility but provides direct services to one or more facility residents.

8 DE Reg. 85 (07/01/04)

15 DE Reg. 81 (07/01/11)

15 DE Reg. 1156 (02/01/12)

4.0 Licensing Requirements And Procedures

- 4.1 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.
- 4.2 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.
- 4.3 Inspections and monitoring shall be conducted in accordance with 16 **Del.C.** Ch. 11, Subchapter I., Licensing By The State.
- 4.4 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.
- 4.5 The Department may impose civil money penalties and/or other enforcement remedies in accordance with the procedures outlined in 16 **Del.C.** Ch. 11, Subchapter I., Licensing by the State.
- 4.6 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.
- 4.7 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.
- 4.8 If a facility or part of a facility plans to close:
 - 4.8.1 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.
 - 4.8.2 The facility staff must notify each resident advising him/her of the action in progress at least 90 days before the planned closure.
 - 4.8.3 The resident must be given the opportunity to designate a preference for a specific facility or for other arrangements.
 - 4.8.4 The assisted living facility must arrange for the relocation to other facilities in the area in accordance with the residents’ preference, if possible.
 - 4.8.5 Any applicant for admission to the assisted living facility shall be advised of the planned closure date.
 - 4.8.6 All residents’ records and any medications must accompany the residents to their new residences.
- 4.9 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.

5.0 General Requirements

- 5.1 All written information provided by the assisted living facility including the written application process shall be accurate, precise, easily understood and readable by a resident, and in compliance with all applicable laws. If an applicant is rejected the facility shall provide clear reasons for the rejection in writing upon request.
- 5.2 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.
- 5.3 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.
- 5.4 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.
- 5.5 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.
- 5.6 The assisted living facility shall arrange for emergency transportation and care.
- 5.7 Inspection summaries and compliance history information shall be posted by the facility in accordance with 16 **Del.C.** Ch. 11, Subchapter I., Licensing by the State.
- 5.8 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.
- 5.9 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:
 - 5.9.1 Require care by a nurse that is more than intermittent or for more than a limited period of time;
 - 5.9.2 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;
 - 5.9.3 Require monitoring of a chronic medical condition that is not essentially stabilized through available medications and treatments;
 - 5.9.4 Are bedridden for more than 14 days;
 - 5.9.5 Have developed stage three or four skin ulcers;
 - 5.9.6 Require a ventilator;
 - 5.9.7 Require treatment for a disease or condition which requires more than contact isolation;
 - 5.9.8 Have an unstable tracheostomy or have a stable tracheostomy of less than 6 months' duration;
 - 5.9.9 Have an unstable peg tube;
 - 5.9.10 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:
 - 5.9.10.1 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.
 - 5.9.10.2 The facility shall document the presence of the port on the Uniform Assessment Instrument, the service plan, interagency referrals and any facility reports,
 - 5.9.10.3 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;
 - 5.9.11 Wander such that the assisted living facility would be unable to provide adequate supervision and/or security arrangements;
 - 5.9.12 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
 - 5.9.13 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.

- 5.10 The provisions of section 5.9 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.
- 5.11 The Assisted Living facility shall cooperate fully with the state protection and advocacy agency, as defined in 16 **Del.C.** §1102(7), in fulfilling functions authorized by Title 16, Chapter 11.
- 5.12 An assisted living facility that provides direct healthcare services to persons diagnosed as having Alzheimer's disease or other forms of dementia shall provide dementia specific training each year to those healthcare providers who must participate in continuing education programs. The mandatory training must include: communicating with persons diagnosed as having Alzheimer's disease or other forms of dementia; the psychological, social, and physical needs of those persons; and safety measures which need to be taken with those persons. This paragraph shall not apply to persons certified to practice medicine under the Medical Practice Act, Chapter 17 of Title 24 of the Delaware Code.

8 DE Reg. 85 (07/01/04)

13 DE Reg. 1328 (04/01/10)

14 DE Reg. 1360 (06/01/11)

15 DE Reg. 192 (08/01/11)

6.0 Resident Waivers

- 6.1 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 5.9. A waiver request shall contain documentation by a physician stating that the resident's condition is expected to improve within 90 days.
- 6.2 The facility shall provide interim needed services by appropriate health care professionals while any waiver request is pending.
- 6.3 The assisted living facility shall submit in writing a request for a waiver, which shall include the following information:
 - 6.3.1 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;
 - 6.3.2 An explanation of why denial of the waiver will impose a substantial hardship for the resident;
 - 6.3.3 An explanation of why the waiver will not adversely affect the resident for whom the waiver is sought or other residents; and
 - 6.3.4 The duration of the waiver, not to exceed 90 days for each incident or condition.
- 6.4 In evaluating a waiver request submitted under this regulation, the Department shall review the statements in the application and may:
 - 6.4.1 Inspect the assisted living facility;
 - 6.4.2 Confer with the Assisted Living Director or his/her designee;
 - 6.4.3 Discuss the request with the resident to determine whether he/she believes a waiver is in his/her best interest; and/or
 - 6.4.4 Review other waivers currently in place at the assisted living facility.
- 6.5 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.
- 6.6 If an assisted living facility violates any condition of a waiver, or if it appears to the Department that the health or safety of the resident will be adversely affected by the continuation of a waiver, the Department may revoke it. The revocation may be appealed; however, transfer or discharge procedures in accordance with 16 **Del.C.** §1121(18), shall be commenced immediately.

15 DE Reg. 81 (07/01/11)

7.0 Specialized Care for Memory Impairment

- 7.1 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.

- 7.2 Said disclosure shall be made to the Department and to any person seeking specialized care for memory impairment in an assisted living facility.
- 7.3 The information disclosed shall explain the additional care that is provided in each of the following areas:
- 7.3.1 Philosophy: a written statement of the agency's overall philosophy and mission which reflects the needs of residents affected by memory impairment;
 - 7.3.2 Resident Population: a description of the resident population to be served; the service agreement and its implementation;
 - 7.3.3 Pre-Admission, Admission & Discharge: the process and criteria for placement, transfer or discharge from this specialized care;
 - 7.3.4 Assessment, Care Planning & Implementation: the process used for assessment and establishing and updating the service agreement and its implementation;
 - 7.3.5 Staffing Plan & Training Policies: staffing plan, orientation, and regular in-service education for specialized care;
 - 7.3.6 Physical Environment: the physical environment and design features, including security systems, appropriate to support the functioning of adults with memory impairment;
 - 7.3.7 Resident Activities: the frequency and types of resident activities;
 - 7.3.8 Family Role in Care: the family involvement and family support programs;
 - 7.3.9 Psychosocial Services: the process for addressing the mental health, behavior management, and social functioning needs of the resident;
 - 7.3.10 Nutrition/Hydration: the frequency and types of nutrition and hydration services provided; and
 - 7.3.11 Program Costs: the cost of care and any additional fees.
- 7.4 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.

8.0 Medication Management

- 8.1 An assisted living facility shall establish and adhere to written medication policies and procedures which shall address:
- 8.1.1 Obtaining and refilling medication;
 - 8.1.2 Storing and controlling medication;
 - 8.1.3 Disposing of medication; and
 - 8.1.4 Administration of medication, self-administration of medication, assistance with self-administration of medication, and medication management by an adult family member/support person.
 - 8.1.5 Provision for a quarterly pharmacy review conducted by a pharmacist which shall include:
 - 8.1.5.1 Assisting the facility with the development and implementation of medication-related policies and procedures;
 - 8.1.5.2 Physical inspection of the medication storage areas;
 - 8.1.5.3 Review of each resident's medication regimen with written reports noting any identified irregularities or areas of concern.
- 8.2 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.
- 8.3 Medication stored by the assisted living facility shall be stored and controlled as follows:
- 8.3.1 Medication shall be stored in a locked container, cabinet, or area that is only accessible to authorized personnel;
 - 8.3.2 Medication that is not in locked storage shall not be left unattended and shall not be accessible to unauthorized personnel;
 - 8.3.3 Medication shall be stored in the original labeled container;
 - 8.3.4 A bathroom or laundry room shall not be used for medication storage; and
 - 8.3.5 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.
- 8.4 Residents who self-administer medication shall be provided with a lockable container or cabinet. This requirement does not apply to medications which are kept in the immediate control of the individual resident, such as in a pocket or in a purse. Facility policies must require that medications be secured in a locked container or in a locked room.

- 8.5 A separate medication log must be maintained for each resident documenting administration of medication by staff and staff assistance with self-administration.
- 8.6 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.
- 8.7 The assisted living facility shall ensure that the review required by section 8.6 is documented in the resident's records, including any recommendations given by the reviewer.
- 8.8 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:
 - 8.8.1 Medications are properly labeled, stored and maintained;
 - 8.8.2 Each resident receives the medications that have been specifically prescribed in the manner that has been ordered;
 - 8.8.3 The desired effect of each medication is achieved, and if not, that the appropriate authorized prescriber is so informed;
 - 8.8.4 Any undesired side effects, adverse drug reactions, and medication errors are identified and reported to the appropriate authorized prescriber; and
 - 8.8.5 Any unresolved discrepancy of controlled substances shall be reported to the Delaware Office of Narcotics and Dangerous Drugs.
- 8.9 Records shall be kept on file at the facility for those who have completed the AWSAM course which is required by 24 **Del.C.** Ch. 19 for those who assist the residents with self-administration of medication.
- 8.10 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.** Ch. 19.

13 DE Reg. 1328 (04/01/10)

15 DE Reg. 81 (07/01/11)

9.0 Infection Control

- 9.1 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:
 - 9.1.1 The necessary precautions stated in the written procedures are followed; and
 - 9.1.2 All rules of the Delaware Division of Public Health are followed so there is minimal danger of transmission to staff and residents.
- 9.2 Any resident found to have active tuberculosis in an infectious stage may not continue to reside in an assisted living facility.
- 9.3 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.
- 9.4 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.
 - 9.4.1 The assisted living facility shall have policies and procedures for infection control as it pertains to staff, residents, and visitors.
 - 9.4.2 All assisted living facility staff shall be required to use Standard Precautions.
- 9.5 Requirements for tuberculosis and immunizations:
 - 9.5.1 The facility shall have on file the results of tuberculin testing performed on all newly placed residents.
 - 9.5.2 Minimum requirements for pre-employment 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.

- 9.5.2.1 No person, including volunteers, found to have active tuberculosis in an infectious stage shall be permitted to give care or service to residents.
- 9.5.2.2 Any person having a positive skin test but a negative X-ray shall receive an annual evaluation for signs and symptoms of active TB if they cannot provide documentation of completion of treatment for LTBI (latent TB infection).
- 9.5.2.3 Persons with a prior BCG vaccination are required to be tested as set forth in 9.5.2.
- 9.5.2.4 A report of all test results shall be kept on file at the facility of employment.

9.6 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.

9.7 The assisted living facility shall have on file evidence of vaccination against pneumococcal pneumonia for all residents older than 65 years, or those who received the pneumococcal vaccine before they became 65 years and 5 years have elapsed, 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.

9.8 Specific Requirements for COVID-19:

9.8.1 Residents

- 9.8.1.1 All residents should be tested upon identification of another resident with symptoms consistent with COVID-19, or if facility staff have tested positive for COVID-19.
- 9.8.1.2 All other resident testing should be consistent with Division of Public Health guidance for the duration of the public health emergency.
- 9.8.1.3 All testing and test results must be documented in the resident medical record.
- 9.8.1.4 Facilities must report all resident testing and test results, to the Delaware Division of Public Health.

9.8.2 Staff, vendors and volunteers

~~[9.8.2.1 All staff, vendors and volunteers who have not previously tested positive for COVID-19 must receive a baseline COVID-19 test within 2 weeks of the effective date of this regulation.~~

~~9.8.2.2.1~~ 9.8.2.1 All Prior to their start date, all] new staff, vendors and volunteers [who cannot provide proof of previous positive testing must be tested prior to their start date must be tested in accordance with the Delaware Division of Public Health guidance].

~~[9.8.2.3]~~ 9.8.2.2] All staff, vendors and volunteers who test negative must be retested consistent with Division of Public Health guidance for the duration of the public health emergency.

~~[9.8.2.4]~~ 9.8.2.3] Facilities must report all staff, vendor and volunteer testing and test results, to the Delaware Division of Public Health.

~~[9.8.2.5]~~ 9.8.2.4] Facilities must follow recommendations of the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services and the Division of Public Health regarding the provision of care or services to residents by staff, vendor or volunteer found to be positive for COVID-19 in an infectious stage.

~~[9.8.2.6]~~ 9.8.2.5] Facilities shall amend their policies and procedures to include:

~~[9.8.2.6.1]~~ 9.8.2.5.1] Work exclusion and return to work protocols for staff tested positive for COVID-19.

~~[9.8.2.6.2]~~ 9.8.2.5.2] Staff refusals to participate in COVID-19 testing.

~~[9.8.2.6.3]~~ 9.8.2.5.3] Staff refusals to authorize release of their testing results to the facility.

~~[9.8.2.6.4]~~ 9.8.2.5.4] Procedures to obtain staff authorizations for release of laboratory test results to the facility so as to inform infection control and prevention strategies.

~~[9.8.2.6.5]~~ 9.8.2.5.5] Plans to address staffing shortages and facility demands should a COVID-19 outbreak occur.

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- 10.1 The assisted living facility shall supply a written contract that is precise, easily understood and readable by a resident, and in compliance with all applicable laws.
- 10.2 The assisted living facility shall recommend review of the contract by an attorney or other representative chosen by the resident.
- 10.3 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.
- 10.4 The resident shall sign a contract within 3 business days after admission that:
 - 10.4.1 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;
 - 10.4.2 Is accurate, precise, legible, and written in plain language; and
 - 10.4.3 Conforms to all relevant state and local laws and regulations.
- 10.5 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.
- 10.6 The contract or service agreement shall include, at a minimum, the following non-financial provisions:
 - 10.6.1 A listing of basic and optional services provided by the assisted living facility including the availability of licensed nursing staff;
 - 10.6.2 A listing of optional services that may be provided by third parties;
 - 10.6.3 A statement of the resident's rights, as set forth in 16 Del.C. Ch. 11, Subchapter II and an explanation of the assisted living facility's grievance procedures;
 - 10.6.4 Occupancy provisions, including:
 - 10.6.4.1 Policies regarding bed and room assignment, including the specific room and bed assigned to the resident at the time of admission;
 - 10.6.4.2 Policies regarding residents modifying their living area;
 - 10.6.4.3 Procedures to be followed when the assisted living facility temporarily or permanently changes the resident's accommodation by:
 - 10.6.4.3.1 Relocating the resident within the facility;
 - 10.6.4.3.2 Making a change in roommate assignment; and
 - 10.6.4.3.3 Increasing or decreasing the number of individuals occupying a room.
 - 10.6.4.4 Procedures to be followed in transferring the resident to another facility;
 - 10.6.4.5 Security procedures which the licensee shall implement to protect the resident and the resident's property;
 - 10.6.4.6 The staff's right to enter a resident's room;
 - 10.6.4.7 The resident's rights and obligations concerning use of the facility, including common areas;
 - 10.6.4.8 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;
 - 10.6.4.9 Provisions for interim service in the event of an emergency; and
 - 10.6.4.10 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.
 - 10.6.5 Discharge/temporary absence policies and procedures, including:
 - 10.6.5.1 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;
 - 10.6.5.2 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;
 - 10.6.5.3 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;
 - 10.6.5.4 The procedures which the assisted living facility shall follow in helping the resident find an appropriate placement;

- 10.6.5.5 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.
- 10.6.6 Obligations of the facility and the resident as to:
 - 10.6.6.1 Arranging for or overseeing medical care; and
 - 10.6.6.2 Monitoring of the status of the resident.
- 10.6.7 The assisted living facility's formal internal grievance process which shall protect residents from reprisal by the facility or its employees.
- 10.6.8 An inventory of the resident's personal belongings, if the resident so desires.
- 10.7 The contract shall include, at a minimum, the following financial provisions:
 - 10.7.1 Party responsible for:
 - 10.7.1.1 Handling the finances of the resident;
 - 10.7.1.2 Purchasing or renting essential or desired equipment and supplies;
 - 10.7.1.3 Arranging and contracting for services not covered by the contract;
 - 10.7.1.4 Ascertaining the cost of and purchasing durable medical equipment; and
 - 10.7.1.5 Disposing of the resident's property upon discharge or death of the resident.
 - 10.7.2 Rate structure and payment provisions including:
 - 10.7.2.1 All rates to be charged to the resident, including, but not limited to:
 - 10.7.2.1.1 Service packages;
 - 10.7.2.1.2 Fee for service rates; and
 - 10.7.2.1.3 Other ancillary charges.
 - 10.7.2.2 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;
 - 10.7.2.3 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;
 - 10.7.2.4 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;
 - 10.7.2.5 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
 - 10.7.2.6 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.
- 10.8 The contract shall be amended by the parties to reflect any applicable increase or decrease in charges. Modification may be done by an addendum to the contract.
- 10.9 All notices to be provided pursuant to an assisted living contract shall be in writing and mailed or hand-delivered to the resident.
- 10.10 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.

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11.0 Resident Assessment

- 11.1 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.
- 11.2 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.
- 11.3 Within 30 days prior to admission, a prospective resident shall have a medical evaluation completed by a physician.
- 11.4 The resident assessment shall be completed in conjunction with the resident.

- 11.5 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.
- 11.6 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.
- 11.7 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.

12.0 Services

- 12.1 The assisted living facility shall ensure that:
 - 12.1.1 Three meals, snacks and prescribed food supplements are available during each 24-hour period, 7 days per week;
 - 12.1.2 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;
 - 12.1.3 Food service complies with the Delaware Food Code; and
 - 12.1.4 A resident who chooses not to follow prescribed dietary recommendations shall be provided documented counseling on potential adverse outcomes.
- 12.2 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.
- 12.3 The assisted living facility shall ensure that the resident's service agreement is being properly implemented.
- 12.4 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.
- 12.5 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.
- 12.6 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.
- 12.7 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.

13.0 Service Agreements

- 13.1 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.
- 13.2 The service agreement or contract shall address the physical, medical, and psychosocial services that the resident requires as follows:
 - 13.2.1 Assistance with activities of daily living and instrumental activities of daily living;
 - 13.2.2 Services provided by licensed nurses;
 - 13.2.3 Food, nutrition, and hydration services;
 - 13.2.4 Environmental services including housekeeping, laundry, safety, trash removal;
 - 13.2.5 Psychosocial/emotional services including those related to memory impairment and other cognitive deficits;
 - 13.2.6 Banking, record keeping, and personal spending services;
 - 13.2.7 Transportation services;
 - 13.2.8 Individual living unit furnishings;
 - 13.2.9 Notification procedures when an incident occurs or there is a change in the health status of the resident;
 - 13.2.10 Assistive technology and durable medical equipment;
 - 13.2.11 Rehabilitation services;

- 13.2.12 Qualified interpreters for people who have a hearing impairment or do not speak English; and
- 13.2.13 Reasonable accommodations for persons with disabilities as defined by applicable state and federal law.
- 13.3 The resident's personal attending physician(s) shall be identified in the service agreement by name, address, and telephone number.
- 13.4 The facility shall be responsible for appropriate documentation in the service agreement for services provided or arranged by the facility.
- 13.5 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.
- 13.6 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.
- 13.7 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.
- 13.8 The following are criteria for a managed/ negotiated risk agreement:
 - 13.8.1 The risks are tolerable to all parties participating in the development of the managed/negotiated risk agreement;
 - 13.8.2 Mutually agreeable action is negotiated to provide the greatest amount of resident autonomy with the least amount of risk; and
 - 13.8.3 The resident living in the facility is capable of making choices and decisions and understanding consequences.
- 13.9 If a managed/negotiated risk agreement is made a part of the service agreement, it shall:
 - 13.9.1 Clearly describe the problem, issue or service that is the subject of the managed/negotiated risk agreement;
 - 13.9.2 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;
 - 13.9.3 Indicate the agreed-upon option;
 - 13.9.4 Describe the agreed upon responsibilities of the assisted living facility, the resident, and any third parties;
 - 13.9.5 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
 - 13.9.6 Include a time frame for review.
- 13.10 The assisted living facility shall have sufficient staff to meet its responsibilities under the managed/negotiated risk agreement.
- 13.11 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.
- 13.12 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.

14.0 Resident Rights

- 14.1 Assisted living facilities are required by 16 **Del.C.** Ch. 11, Subchapter II, to comply with the provisions of the Rights of Patients covered therein.
- 14.2 Each resident has the right of privacy in his/her room, including a door that locks, consistent with the safety needs of the resident.

15.0 Quality Assurance

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.

16.0 Staffing

- 16.1 As used herein "staff" includes permanent employees of the assisted living facility and independent contractors, including "temps."
- 16.2 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.
- 16.3 All direct care staff shall be familiar with the service agreement for each resident for whom they provide care.
- 16.4 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.
- 16.5 The Nursing Home Administrator shall comply with the provisions of 24 **Del.C.** Ch. 52, and the Board's Rules and Regulations.
- 16.6 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.
- 16.7 The Director of a facility for 4 beds or fewer shall meet one of the following criteria:
 - 16.7.1 A baccalaureate degree in a health or social services field or business administration; or
 - 16.7.2 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
 - 16.7.3 An RN with a combined total of 4 years full-time equivalent education and related work experience; or
 - 16.7.4 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.
- 16.8 The Director of a Facility for 4 beds or fewer shall be on-site at least 8 hours a week.
- 16.9 Each facility for 4 beds or fewer shall have a full-time, on-site house manager who shall at a minimum:
 - 16.9.1 Possess a high school diploma or its equivalent;
 - 16.9.2 Be certified as a CNA with at least three years experience providing care in a health care setting;
 - 16.9.3 Complete an orientation program in accordance with the CNA regulations; and
 - 16.9.4 Receive, at a minimum, 12 hours of regular in-service education annually, which may include but not be limited to the topics listed below:
 - 16.9.4.1 The health and psychosocial needs of the population being served;
 - 16.9.4.2 The resident assessment process;
 - 16.9.4.3 Use of service agreements;
 - 16.9.4.4 Cuing, coaching, and monitoring residents who self-administer medications, with or without assistance;
 - 16.9.4.5 Providing assistance with ambulation, personal hygiene, dressing, toileting, and feeding;
 - 16.9.4.6 16 **Del.C.** Ch. 11, pertaining to resident's rights; reporting of abuse, neglect, mistreatment, and financial exploitation; and the Ombudsman Program;
 - 16.9.4.7 Fire and life safety, and emergency disaster plans;
 - 16.9.4.8 Infection control, including Standard Precautions;
 - 16.9.4.9 Basic food safety;
 - 16.9.4.10 Basic first aid, CPR, and the Heimlich Maneuver; and
 - 16.9.4.11 Hospice services.
- 16.10 Assisted living facilities administering therapies and/or treatments shall have staff adequate in number and appropriately qualified and/or licensed.
- 16.11 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.
- 16.12 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.
- 16.13 The Director of Nursing shall have overall responsibility for the coordination, supervision and provision of the nursing department /services.

- 16.14 Assisted living facility resident assistants shall, at a minimum:
 - 16.14.1 Be at least 18 years old;
 - 16.14.2 Participate in a facility-specific orientation program that covers the following topics:
 - 16.14.2.1 Fire and life safety, and emergency disaster plans;
 - 16.14.2.2 Infection control, including Standard Precautions;
 - 16.14.2.3 Basic food safety;
 - 16.14.2.4 Basic first aid and the Heimlich Maneuver;
 - 16.14.2.5 Job responsibilities;
 - 16.14.2.6 The health and psychosocial needs of the population being served;
 - 16.14.2.7 The resident assessment process; and
 - 16.14.2.8 The use of service agreements;
 - 16.14.2.9 16 **Del.C.** Ch. 11, pertaining to residents' rights; reporting of abuse, neglect, mistreatment, and financial exploitation; and the Ombudsman Program;
 - 16.14.2.10 Hospice services.
 - 16.14.3 Receive, at a minimum, 12 hours of regular in-service education annually which may include but not be limited to the topics listed in 16.14.2;
 - 16.14.4 Receive training to competently assist in activities of daily living or provide documentation of such training, and
 - 16.14.5 Complete a Delaware Board of Nursing-approved AWSAM training course if assisting with self-administration of medications.
- 16.15 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.
- 16.16 The assisted living facility shall maintain staffing records which document what personnel were on duty as well as specific hours worked for each day.
- 16.17 The assisted living facility shall maintain a copy of each employee's signature and handwritten initials.
- 16.18 The assisted living facility shall maintain records of each employee's regular in-service education hours.
- 16.19 The assisted living facility shall provide orientation training to all new staff.
- 16.20 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:
 - 16.20.1 Tour of the facility;
 - 16.20.2 Fire and disaster plans;
 - 16.20.3 Emergency equipment and supplies;
 - 16.20.4 Communication and documentation requirements of the facility;
 - 16.20.5 Process for reporting emergencies and change of condition; and
 - 16.20.6 Review of current assigned resident issues/ needs.
- 16.21 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.
- 16.22 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.
- 16.23 Written policies and procedures shall be required and adhered to for any assisted living facility utilizing volunteers.

17.0 Environment and Physical Plant

- 17.1 Each assisted living facility shall comply with applicable federal, state and local laws including:
 - 17.1.1 Rehabilitation Act, Section 504;
 - 17.1.2 Fair Housing Act as amended; and
 - 17.1.3 Americans with Disabilities Act.
- 17.2 Assisted living facilities shall:
 - 17.2.1 Be in good repair;
 - 17.2.2 Be clean;
 - 17.2.3 Have a hazard-free environment; and
 - 17.2.4 Have an effective pest control program.

- 17.3 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.
- 17.4 Common areas shall be lighted to assure resident safety.
- 17.5 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.
 - 17.5.1 Sharing of a bedroom shall be limited to 2 residents;
 - 17.5.2 Each facility shall have locked storage available for the resident's valuables, in accordance with the facility's policies;
 - 17.5.3 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.
- 17.6 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:
 - 17.6.1 A clean and sanitary environment;
 - 17.6.2 Safe storage of food; and
 - 17.6.3 A means to enable hand washing and sanitizing of dishes, utensils and food preparation equipment.
- 17.7 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.
- 17.8 Hot water at resident bathing and hand-washing facilities shall not exceed 120 degrees Fahrenheit.

8 DE Reg. 85 (07/01/04)

18.0 Emergency Preparedness

- 18.1 Nursing facilities shall comply with the rules and regulations adopted and enforced by the State Fire Prevention Commission or the municipality with jurisdiction.
- 18.2 Regular fire drills shall be held at least quarterly on each shift. Written records shall be kept of attendance at such drills.
- 18.3 Each facility shall develop and maintain all-hazard emergency plans for evacuation and sheltering in place. The plan must be submitted to the Division and DEMA in a digital format and it must conform to the template prescribed by the Division. The all-hazard emergency plan must include plans to address staffing shortages and facility demands.
- 18.4 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.
- 18.5 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.
- 18.6 Each facility shall submit with an application for a license and annual renewal of a license:
 - 18.6.1 A current all hazards emergency plan, and
 - 18.6.2 Copies of the FEMA certificate of achievement which demonstrate that at least two active, full-time employees have completed FEMA training in ICS-100 and NIMS-700a in the past 24 months.
- 18.7 The Division may grant an extension of time for either requirement in 18.6 upon request and for good cause shown.

16 DE Reg. 865 (02/01/13)

19.0 Records and Reports

- 19.1 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.
- 19.2 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.
- 19.3 The assisted living facility resident clinical records shall be retained for a minimum of 5 years following discharge or 3 years after death before being destroyed.

- 19.4 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:
 - 19.4.1 There is a written policy, at the assisted living facility, describing the attestation policy(ies) force at the facility;
 - 19.4.2 The computer has built-in safeguards to minimize the possibility of fraud;
 - 19.4.3 Each person responsible for an attestation has an individualized identifier;
 - 19.4.4 The date and time is recorded from the computer's internal clock at the time of entry;
 - 19.4.5 An entry is not to be changed after it has been recorded; and
 - 19.4.6 The computer program controls what sections/ areas any individual can access/enter data based on the individual's personal identifier.
- 19.5 Incident reports, with adequate documentation, shall be completed for each incident. Records of incident reports shall be retained in facility files for the following:
 - 19.5.1 All reportable incidents.
 - 19.5.2 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.
 - 19.5.3 Errors or omissions in treatment or medication.
 - 19.5.4 Injuries of unknown source.
 - 19.5.5 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.
- 19.6 Reportable incidents shall be reported immediately, which shall be within 8 hours of the occurrence of the incident, to the Division. The method of reporting shall be as directed by the Division.
- 19.7 Reportable incidents include:
 - 19.7.1 Abuse as defined in 16 **Del.C.** §1131.
 - 19.7.1.1 Physical abuse.
 - 19.7.1.1.1 Staff to resident with or without injury.
 - 19.7.1.1.2 Resident to resident with or without injury.
 - 19.7.1.1.3 Other (e.g., visitor, relative) to resident with or without injury.
 - 19.7.1.2 Sexual abuse.
 - 19.7.1.2.1 Staff to resident sexual acts.
 - 19.7.1.2.2 Resident to resident non-consensual sexual acts.
 - 19.7.1.2.3 Other (e.g., visitor, relative) to resident non-consensual sexual acts.
 - 19.7.1.3 Emotional abuse.
 - 19.7.1.3.1 Staff to resident.
 - 19.7.1.3.2 Resident to resident.
 - 19.7.1.3.3 Other (e.g., visitor, relative) to resident.
 - 19.7.2 Neglect as defined in 16 **Del.C.** §1131.
 - 19.7.3 Mistreatment as defined in 16 **Del.C.** §1131.
 - 19.7.4 Financial exploitation as defined in 16 **Del.C.** §1131.
 - 19.7.5 Resident elopement.
 - 19.7.5.1 Any circumstance in which a resident's whereabouts are unknown to staff and the resident suffers harm.
 - 19.7.5.2 Any circumstance in which a cognitively impaired resident, whose whereabouts are unknown to staff, exits the facility.
 - 19.7.5.3 Any circumstance in which a resident cannot be found inside or outside a facility and the police are summoned.
 - 19.7.6 Death of a resident in a facility or within 5 days of transfer to an acute care facility.
 - 19.7.7 Significant injuries.

- 19.7.7.1 Injury from an incident of unknown source in which the initial investigation concludes that there is reasonable basis to suspect that the injury is suspicious. An injury is suspicious based on; 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.
- 19.7.7.2 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.
- 19.7.7.3 Injury sustained while a resident is physically restrained.
- 19.7.7.4 Injury sustained by a resident dependent on staff for toileting, mobility, transfer and/or bathing.
- 19.7.7.5 Medication error or omission which causes or prolongs the resident's discomfort, jeopardizes the resident's health or safety, or requires periodic reassessment of the resident's clinical status by facility professional staff.
- 19.7.7.6 Treatment error or omission which causes or prolongs the resident's discomfort, jeopardizes the resident's health or safety, or requires periodic reassessment of the resident's clinical status by facility professional staff.
- 19.7.7.7 A burn greater than first degree.
- 19.7.7.8 Choking resulting in transfer to an acute care facility.
- 19.7.7.9 Areas of contusions or lacerations which may be attributable to abuse or neglect.
- 19.7.7.10 Serious unusual and/or life-threatening injury.
- 19.7.8 Attempted suicide.
- 19.7.9 Poisoning.
- 19.7.10 Epidemic outbreak or quarantine.
- 19.7.11 Circumstances which provide a reasonable basis to suspect that a resident's drugs have been diverted.
- 19.7.12 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.
- 19.7.13 Structural damage or unsafe structural conditions.
 - 19.7.13.1 Structural damage to a facility due to natural disasters such as hurricanes, tornadoes, flooding or earthquakes.
 - 19.7.13.2 Water damage which impacts resident health, safety or comfort.

8 DE Reg. 85 (07/01/04)

13 DE Reg. 1328 (04/01/10)

15 DE Reg. 1156 (02/01/12)

20.0 Waivers and Severability

- 20.1 Waivers may be granted by the Division for good cause.
- 20.2 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.

6 DE Reg. 525 (10/01/02)

14 DE Reg. 1190 (05/01/11)

15 DE Reg. 81 (07/01/11)

15 DE Reg. 1156 (02/01/12)

16 DE Reg. 865 (02/01/13)

24 DE Reg. 579 (12/01/20) (Final)