

CABINET FOR HEALTH AND FAMILY SERVICES

Office of Inspector General

Division of Health Care

(Amended After Comments)

902 KAR 20:480. Assisted living communities.

RELATES TO: KRS 194A.700—194A.729, ~~209.030(2) — (4)~~, 209.032, 216.515, 216.530, 216.532, 216.595, 216.718, 216.765, 216.789, 216B.015(13), 216B.020(1), 216B.105, 216B.160, 216B.165, 218A.200(6), ~~314.011(3)~~, 21 C.F.R. Part 1317, 45 C.F.R. Parts 160, 164, 42 U.S.C. 1320d-2–1320d-8

STATUTORY AUTHORITY: KRS 194A.707(1), (9), 216B.042(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 194A.707(1) requires the Cabinet for Health and Family Services to promulgate administrative regulations under KRS Chapter 13A for an initial and re-licensure review process for assisted living communities. KRS 194A.707(9) permits the cabinet to promulgate administrative regulations to establish an assisted living community and assisted living community with dementia care licensure fee that shall not exceed costs of the program to the cabinet. KRS 216B.042(1) requires the cabinet to promulgate administrative regulations necessary for the proper administration of the licensure function, which includes establishing licensure standards and procedures to ensure safe, adequate, and efficient health facilities and health services. This administrative regulation establishes the minimum licensure requirements for the operation of social model assisted living communities (ALC), assisted living communities that provide basic health and health-related services (ALC-BH), and assisted living communities with a secured dementia care unit (ALC-DC).

Section 1. Definitions.

- (1) "Activities of daily living" is defined by KRS 194A.700(1).
- (2) "Ambulatory" is defined by KRS 194A.700(2).
- (3) "Assistance with activities of daily living and instrumental activities of daily living" is defined by KRS 194A.700(3).
- (4) "Assistance with self-administration of medication" is defined by KRS 194A.700(4).
- (5) "Assisted living community" is defined by KRS 194A.700(5).
- (6) "Assisted living community with dementia care" is defined by KRS 194A.700(6).
- (7) "Assisted living services" is defined by KRS 194A.700(7).
- (8) "Basic health and health-related services" is defined by KRS 194A.700(8).
- (9) "Dementia" is defined by KRS 194A.700(10).
- (10) "Dementia care services" is defined by KRS 194A.700(11).
- (11) "Dementia-trained staff" is defined by KRS 194A.700(12).
- (12) "Direct care service" is defined by KRS 216.718(4).
- (13) "Hands-on assistance" is defined by KRS 194A.700(13).
- (14) "Health facility" is defined by KRS 216B.015(13) to include assisted living communities.

(15) "Immediate family member" means a:

- (a) Spouse;**
- (b) Child;**
- (c) Stepchild;**
- (d) Son-in-law;**
- (e) Daughter-in-law; or**
- (f) Grandchild.**

- (16) ~~+(15)+~~** "Instrumental activities of daily living" is defined by KRS 194A.700(15).

~~(17)~~ ~~((16))~~ "Legal representative" means a person legally responsible for representing or standing in the place of the resident for the conduct of the resident's affairs.

~~(18)~~ **"Licensed health professional" means a person who:**

~~(a)~~ **Possesses a current Kentucky license or multistate licensure privilege to practice in Kentucky; and**

~~(b)~~ **Provides services to ALC-BH or ALC-DC residents, including the delegation of tasks pursuant to KRS 194A.700(7)(h) as authorized under the professional's scope of practice.**

~~(19)~~ ~~((17))~~ "Living unit" is defined by KRS 194A.700(16).

~~(20)~~ ~~((18))~~ "Managing agent" means an individual or legal entity designated by the licensee through a management agreement to act on behalf of the licensee in the on-site management of the assisted living community.

~~(21)~~ ~~((19))~~ "Medication administration" is defined by KRS 194A.700(17).

~~(22)~~ ~~((20))~~ "Medication management" is defined by KRS 194A.700(18).

~~(23)~~ ~~((21))~~ "Medication reconciliation" means the process of identifying the most accurate list of all medications the resident is taking, including the name, dosage, frequency, and route, by comparing the resident record to an external list of medications obtained from the resident, hospital, prescriber, or other provider.

~~(24)~~ ~~((22))~~ "Medication setup" is defined by KRS 194A.700(19).

~~(25)~~ **"Nurse" is defined by KRS 314.011(3).**

~~(26)~~ **"Nursing task" is defined by 201 KAR 20:400, Section 1(11).**

~~(27)~~ ~~((23))~~ "Person-centered care" is defined by KRS 194A.700(21).

~~(28)~~ ~~((24))~~ "Resident" is defined by KRS 194A.700(22).

~~(29)~~ ~~((25))~~ "Secured dementia care unit" is defined by KRS 194A.700(23).

~~(30)~~ ~~((26))~~ "Service plan" is defined by KRS 194A.700(24).

~~(31)~~ ~~((27))~~ "Significant financial interest" is defined as the lawful ownership of an out-of-state or a Kentucky-licensed health facility or health service, or other entity regulated by the cabinet, whether by share, contribution, or otherwise in an amount equal to or greater than twenty-five (25) percent of total ownership of the out-of-state or Kentucky-licensed health facility or health service, or other cabinet-regulated entity.

~~(32)~~ ~~((28))~~ "Temporary condition" is defined by KRS 194A.700(26).

~~(33)~~ ~~((29))~~ "Unlicensed personnel" is defined by KRS 194A.700(27).

~~(34)~~ **"Volunteer" means a person who has duties that are equivalent to the duties of an employee providing direct care services and the duties involve, or involve, one-on-one contact with a resident a member of a community-based or faith-based organization or group that provides volunteer services that do not involve unsupervised interaction with a resident.**

Section 2. Licensure Categories.

(1) The licensure categories established by this administrative regulation include the following:

(a) A social model assisted living community (ALC) license for any facility that provides assisted living services, excluding basic health and health-related services;

(b) An assisted living community with basic health care (ALC-BH) license for any facility that:

1. Provides assisted living services, including basic health and health-related services directly to its residents; and

2. Does not have a secured dementia care unit; and

(c) An ALC with dementia care (ALC-DC) license for any facility that provides assisted living services and dementia care services in a secured dementia unit.

(2) In accordance with KRS 194A.710(3), a license issued under this administrative regulation shall not be assignable or transferable.

(3) In accordance with KRS 194A.704, a personal care home that is in substantial compliance with KRS 194A.703 shall convert its license to an ALC-BH or ALC-DC license, if applicable, by submitting the application, accompanying documentation, and fee required by Section 3(2) of this administrative regulation at least sixty (60) days prior to the date of annual renewal of the facility's personal care home license.

Section 3. Licensure Application and Fees.

(1) In accordance with KRS 216B.020(1), an ALC, ALC-BH, or ALC-DC shall be exempt from certificate of need.

(2) An applicant for a provisional, initial license or annual renewal as an ALC, ALC-BH, or ALC-DC shall submit to the Office of Inspector General:

(a) A completed Application for License to Operate an Assisted Living Community at least sixty (60) days prior to the:

1. Planned opening; or
2. Annual renewal date;

(b) Proof of approval by the State Fire Marshal's office;

(c) A copy of a blank lease agreement that includes the elements required by KRS 194A.713 and any documentation incorporated in the agreement;

(d) An organizational chart that identifies all entities and individuals with a significant financial interest in the prospective or existing licensee, including the relationship with the licensee and with each other;

(e) A description of any special programming that may be provided in accordance with KRS 194A.713(11);

(f) If applying for a provisional, initial license, or if changes have been made since the date of the previous renewal, a copy of the facility's floor plan that shall identify the:

1. Living units, including features that meet the requirements of KRS 194A.703(1);
2. Central dining area;
3. Laundry facility; and
4. Central living room;

(g) Whether in the preceding seven (7) years any individual with a significant financial interest in the entity seeking initial licensure or renewal as an ALC, ALC-BH, or ALC-DC had a significant financial interest in an out-of-state or a Kentucky-licensed health facility or health service, or other entity regulated by the cabinet, that had its license or certificate to operate denied, suspended, revoked, or voluntarily relinquished as the result of an investigation or adverse action that placed patients, residents, or clients at risk of death or serious harm;

(h)

1. A copy of the applicant's compliance history for any other care facility the applicant operates if applying for a provisional, initial license as an:

- a. ALC or ALC-BH; or
- b. ALC-DC that did not have a dementia unit in operation prior to July 14, 2022.

2. Documentation of the applicant's compliance history shall include a copy of all enforcement action issued by the regulatory agency against the care facility including violations, fines, or negative action against the facility's license during the seven (7) year period prior to application for a provisional, initial license; and

(i) A nonrefundable fee made payable to the Kentucky State Treasurer in accordance with the following fee schedule:

Number of Units Initial and Annual Fee

<25	\$500 + \$40 per unit
25-49	\$1,000 + \$40 per unit

50-74	\$1,500 + \$40 per unit
75-99	\$1,750 + \$40 per unit
100 or more	\$2,000 + \$40 per unit

(3)

(a) Name change. An ALC, ALC-BH, or ALC-DC shall:

1. Notify the Office of Inspector General in writing within ten (10) calendar days of the effective date of a change in the facility's name; and
2. Submit a processing fee of twenty-five (25) dollars.

(b) Change of location. An ALC, ALC-BH, or ALC-DC shall not change the location of the facility until an Application for License to Operate an Assisted Living Community accompanied by the documentation and fees required by subsection (2) of this section have been submitted to the Office of Inspector General.

(c) Change in number of living units.

1. An ALC, ALC-BH, or ALC-DC shall submit an Application for License to Operate an Assisted Living Community to the Office of Inspector General:

- a. At least sixty (60) days prior to an increase in the number of living units; and
- b. Accompanied by a fee of sixty (60) dollars per each additional unit.

2. If there is a decrease in the number of living units, an ALC, ALC-BH, or ALC-DC shall notify the Office of Inspector General within sixty (60) days of the decrease.

(d) Change of ownership.

1. The new owner of an ALC, ALC-BH, or ALC-DC shall submit an Application for License to Operate an Assisted Living Community accompanied by a fee of \$500 within ten (10) calendar days of the effective date of the ownership change.

2. A change of ownership for a license shall be deemed to occur if more than twenty-five (25) percent of an existing facility or capital stock or voting rights of a corporation is purchased, leased, or otherwise acquired by one (1) person from another.

(e) Change of managing agent. An ALC, ALC-BH, or ALC-DC shall submit an updated Application for License to Operate an Assisted Living Community accompanied by a fee of twenty-five (25) dollars within ten (10) calendar days of the effective date of a change of managing agents.

(f) Information shared with lending institutions relative to financing for ALC projects. The cabinet's fee for providing information in accordance with KRS 194A.729 shall be \$250.

(g) Voluntary termination of operations.

1. An ALC or ALC-BH shall:

- a. Notify the Office of Inspector General at least sixty (60) days prior to voluntarily relinquishing its license; and
- b. Notify residents at least sixty (60) days prior to closure unless there is a sudden termination due to:

- (i) Fire;
- (ii) Natural disaster; or
- (iii) Closure by a governmental agency.

2. An ALC-DC that elects to voluntarily terminate operations shall:

- a. Relinquish its license; and
- b. Comply with notification requirements and other the steps for voluntary relinquishment established by KRS 194A.7063.

(4) Upon receipt of an application accompanied by the documentation and fees required by subsection (2) or subsection (3)(b), (c), or (d) of this section, the Office of Inspector

General shall:

- (a) Review the application for completeness; and
- (b) Return the application and accompanying licensure fee if:
 - 1. An individual having a significant financial interest in the facility, within the seven (7) year period prior to the application date, had a significant financial interest in an out-of-state or a Kentucky-licensed health facility or health service, or other entity regulated by the cabinet, that had its license or certificate to operate denied, suspended, revoked, or voluntarily relinquished as the result of an investigation or adverse action that placed patients, residents, or clients at risk of death or serious harm; or
 - 2. The cabinet finds that the applicant misrepresented or submitted false information on the application.

Section 4. Regulatory Functions and Authority to Enter Upon the Premises.

- (1) In accordance with KRS 216.530, inspection of an ALC, ALC-BH, or ALC-DC shall be unannounced.
- (2) Licensure review inspections shall be conducted in accordance with the survey intervals established by KRS 194A.707(2).
- (3) Nothing in this administrative regulation shall prevent the cabinet from:
 - (a) Conducting an investigation related to a complaint; or
 - (b) Making an on-site survey of an ALC, ALC-BH, or ALC-DC more often if the cabinet deems necessary.
- (4) An ALC, ALC-BH, or ALC-DC shall be subject to the:
 - (a) Inspection requirements of 902 KAR 20:008, Section 2(12);
 - (b) Procedures for correcting violations established by 902 KAR 20:008, Section 2(13); and
 - (c) Civil monetary penalties imposed under KRS 194A.722(5) for any violation that poses imminent danger to a resident in which substantial risk of death or serious mental or physical harm is present.

Section 5. License Requirements.

- (1) In accordance with KRS 194A.707(3), an entity shall not operate as ALC, ALC-BH, or ALC-DC unless it is licensed.
- (2) The licensee shall be legally responsible for:
 - (a) The management, control, and operation of the facility in accordance with KRS 194A.710(1), regardless of the existence of a management agreement or subcontract; and
 - (b) Compliance with federal, state, and local laws and administrative regulations pertaining to the operation of the ALC, ALC-BH, or ALC-DC.
- (3) An ALC, ALC-BH, or ALC-DC shall not represent that the facility provides any service other than a service it is licensed to provide.
- (4)
 - (a) Upon approving an application, the cabinet shall issue a single license for each building that is operated by the licensee as an ALC, ALC-BH, or ALC-DC, except as provided under paragraph (b) of this subsection.
 - (b)
 - 1. Upon approving an application for an ALC, ALC-BH, or ALC-DC, the cabinet shall issue a single license for two (2) or more buildings on a campus if operated by the same licensee.
 - 2. A license for two (2) or more buildings on a campus shall identify the:
 - a. Address;
 - b. Licensed resident capacity of each building;

- c. Whether any building has residents that receive basic health and health-related services from the licensee; and
- d. Whether any building has a dementia care unit.

Section 6. Physical Plant Requirements.

- (1) An ALC, ALC-BH, and ALC-DC shall comply with the requirements for living units as established by KRS 194A.703, including compliance with applicable building and safety codes as determined by the enforcement authority with jurisdiction.
- (2) Pursuant to KRS 216.595(3), an ALC-DC may request a waiver from the cabinet regarding building requirements to address the specialized needs of individuals with Alzheimer's disease or other brain disorders.
- (3) The request for a waiver shall follow the same process as a facility's request for a variance pursuant to 902 KAR 20:008, Sections 5 and 6.

Section 7. Operations and Services.

- (1) Resident criteria.
 - (a) In accordance with KRS 194A.711, a resident of an ALC, ALC-BH, or ALC-DC shall be ambulatory unless due to a temporary condition.
 - (b) An ALC, ALC-BH, or ALC-DC shall require a medical examination in accordance with KRS 216.765(1) prior to admission of a resident.
 - (c)
 - 1. An ALC, ALC-BH, or ALC-DC shall complete a functional needs assessment in accordance with KRS 194A.705(6) and provide a copy to the resident:
 - a. Upon move-in; and
 - b. As needed with updated information if there is a change in the resident's condition, but no later than once every twelve (12) months.
 - 2. The functional needs assessment shall be administered by a staff person with at least:
 - a. A bachelor's degree in health or human services or a related field;
 - b. An associate's degree in health or human services or a related field and at least one (1) year of experience working with the elderly or conducting assessments; or
 - c. A high school diploma or its equivalency and two (2) years of experience working with the elderly or conducting assessments.
 - 3. The functional needs assessment shall be used to ensure that the prospective or current resident:
 - a. Meets the eligibility criteria pursuant to KRS 194A.711;
 - b. Has at least minimal ability to verbally direct or physically participate in activities of daily living (ADL) or instrumental activities of daily living (IADL) during the time in which assistance is provided;
 - c. Is free from signs and symptoms of any communicable disease that is likely to be transmitted to other residents or staff;
 - d. Does not have any special dietary needs that the facility is unable to meet; and
 - e. Does not require twenty-four (24) hour nursing supervision.
- (2) Minimum requirements. Each ALC, ALC-BH, and ALC-DC shall:
 - (a) Provide each resident with a copy of the resident's rights established by KRS 216.515;
 - (b) Provide each resident with access to the services required by KRS 194A.705(1) according to the lease agreement;
 - (c) Except for a social model ALC, provide each resident with access to basic health and health-related services;
 - (d) Permit a resident to arrange for additional services under direct contract or arrangement with an outside party pursuant to KRS 194A.705(3) if permitted by the policies of the ALC, ALC-BH, or ALC-DC;

- (e) Utilize a person-centered care planning and service delivery process;
 - (f) Provide an emergency response system or personal medical alert device for residents to request assistance twenty-four (24) hours per day, seven (7) days per week;
 - (g) Allow residents the ability to furnish and decorate the resident's unit within the terms of the lease agreement;
 - (h) Allow the resident the right to choose a roommate if sharing a unit;
 - (i) Except for a resident of a secured dementia unit in an ALC-DC, notify the resident that the living unit shall have a lockable entry door in accordance with KRS 194A.703(1)(b). The licensee shall:
 - 1. Provide the locks on the unit;
 - 2. Ensure that only a staff member with a specific need to enter the unit shall have access to the unit and provide advance notice to the resident before entrance, if possible; and
 - 3. Not lock a resident in the resident's unit;
 - (j) Develop and implement a staffing plan for determining staffing levels that:
 - 1. Includes an evaluation conducted at least twice a year of the appropriateness of staffing levels in the facility;
 - 2. Ensures sufficient staffing at all times to meet the scheduled and reasonably foreseeable unscheduled needs of each resident as required by the residents' functional needs assessments and service plans on a twenty-four (24) hour per day basis; and
 - 3. Ensures that the facility can respond promptly and effectively to:
 - a. Individual resident emergencies; and
 - b. Emergency, safety, and disaster situations affecting staff or residents in the facility;
 - (k) Ensure that one (1) or more staff are available twenty-four (24) hours per day, seven (7) days per week, who are responsible for responding to the requests of residents for assistance with health or safety needs;
 - (l) Upon the request of the resident, provide directly or assist with arranging for transportation to:
 - 1. Medical and social services appointments;
 - 2. Shopping; and
 - 3. Recreation;
 - (m) Upon the request of the resident, provide assistance with accessing available community resources and social services;
 - (n) Provide culturally appropriate programs that help:
 - 1. Residents remain connected to their traditional lifeways; and
 - 2. Promote culturally sensitive interactions between staff and residents; and
 - (o) Allow residents to voluntarily engage in one (1) or more IADLs without assistance or with minimal assistance as documented in the resident's service plan, but shall not force a resident to perform IADLs such as housekeeping, shopping, or laundry.
- (3) Lease agreements.
- (a) Upon entering into a lease agreement, each ALC, ALC-BH, and ALC-DC shall inform the resident in writing according to KRS 194A.705(4) about policies relating to the provision of services and contracting or arranging for additional services.
 - (b) A lease agreement entered into between a resident and an ALC, ALC-BH, or ALC-DC shall meet the minimum content requirements of KRS 194A.713.
- (4) Policies and procedures. Each ALC, ALC-BH, and ALC-DC shall maintain written policies and procedures that are up-to-date and address the following:
- (a) Reporting and recordkeeping of alleged or actual cases of abuse, neglect, or exploitation of an adult in accordance with KRS 194A.709 and KRS 209.030(2) ~~+~~ **(4) to the:**

1. Office of Inspector General, Division of Health Care; and
2. Department for Community Based Services;

- (b) A description of dementia or other brain disorder-specific staff training as required by KRS 216.595(2)(i) if the facility provides special care for persons with a medical diagnosis of Alzheimer's disease or other brain disorders;
 - (c) How priority will be given to assist a resident during an emergency if evacuation of the facility is necessary and the resident requires hands-on assistance from another person to walk, transfer, or move from place to place with or without an assistive device pursuant to KRS 194A.717(5);
 - (d) Grievance policies required by KRS 194A.713(14);
 - (e) Except for a social model ALC, a method that incorporates at least four (4) components in an ongoing resident assessment done by a registered nurse or manager's (director) designee in accordance with KRS 216B.160(7);
 - (f) Conducting a functional needs assessment pursuant to KRS 194A.705(6);
 - (g) Infection control practices that address:
 - 1. The prevention of disease transmission; and
 - 2. Cleaning, disinfection, and sterilization methods used for equipment and the environment;
 - (h) Reminders for medications, treatments, or exercises, if applicable;
 - (i) Except for a social model ALC, ensuring that all nurses and ~~licensed~~ health professionals have current and valid licenses to practice;
 - (j) Medication and treatment management, if the facility provides these services;
 - (k) Except for a social model ALC, delegation of:
 - 1. Nursing tasks in accordance with 201 KAR 20:400; ~~by registered nurses~~ or**
 - 2. Therapeutic or other tasks assigned by** other licensed health professionals;
 - (l) Except for a social model ALC, supervision of ~~registered~~ nurses and licensed health professionals;
 - (m) Except for a social model ALC, supervision of unlicensed personnel performing delegated tasks, **which shall include how the facility ensures compliance with the supervision requirements of 201 KAR 20:400, Section 4, if nursing tasks are delegated;**
 - (n) Cardiopulmonary resuscitation unless the policies of the facility state that this procedure is not initiated by its staff, and each resident or prospective resident is informed of the facility's policy pursuant to KRS 194A.719(1)(d); and
 - (o) Compliance with the requirements of KRS 216B.165, including assurance that retaliatory action shall not be taken against a staff member who in good faith reports a resident care or safety problem.
- (5) Resident grievances.
- (a) Each ALC, ALC-BH, and ALC-DC shall post in a conspicuous place:
 - 1. Information about the facility's grievance procedures; and
 - 2. The name, telephone number, and e-mail contact information for the individuals who are responsible for handling resident grievances.
 - (b) The notice shall also have:
 - 1. Contact information for the state long-term care ombudsman; and
 - 2. Information for reporting suspected abuse, neglect, or exploitation of an adult.

Section 8. Business Operations.

- (1) Display of license. The original current license shall be displayed at the main entrance of each ALC, ALC-BH, and ALC-DC.
- (2) Quality management.
 - (a) For purposes of this section, "quality management activity" shall mean evaluating the quality of care by:

1. Periodically reviewing resident services, complaints made, and other issues that have occurred; and
 2. Determining whether changes in services, staffing, or other procedures need to be made to ensure safe and competent services to residents.
- (b) Each ALC, ALC-BH, or ALC-DC shall engage in quality management appropriate to the size of the facility and relevant to the type of services provided.
- (c) Documentation about the facility's quality management activity shall be:
1. Maintained for at least two (2) years; and
 2. Available to the Office of Inspector General at the time of the survey, investigation, or renewal.
- (3) Restrictions.
- (a) An ALC, ALC-BH, ALC-DC, or staff person shall not:
1. Accept a power-of-attorney from a resident for any purpose or accept appointment as a guardian or conservator; or
 2. Borrow a resident's funds or personal or real property or convert a resident's property to the possession of the facility or staff person.
- (b) An ALC, ALC-BH, ALC-DC, or staff person shall not serve as a resident's designated contact person or legal representative unless the staff person is an immediate family member of the resident.
- (4) Resident finances and property.
- (a) An ALC, ALC-BH, or ALC-DC may assist a resident with household budgeting, including paying bills and purchasing household goods, but shall not otherwise manage a resident's property except as described in this subsection.
- (b) If an ALC, ALC-BH, or ALC-DC accepts responsibility for managing a resident's personal funds as evidenced by the facility's written acknowledgment, the facility shall comply with KRS 216.515(8).
- (c) Within thirty (30) days of the effective date of a facility-initiated or resident-initiated termination of housing or services or the death of the resident, the ALC, ALC-BH, or ALC-DC shall:
1. Provide to the resident, resident's legal representative, or resident's designated contact person a final statement of account;
 2. Provide any refunds due; and
 3. Return any money, property, or valuables held in trust or custody by the facility.

Section 9. Dietary Services.

- (1)
- (a) Dining area. Access to central dining shall be provided for residents of an ALC, ALC-BH, or ALC-DC in accordance with KRS 194A.703(2), including three (3) meals and snacks made available each day in accordance with KRS 194A.705(1)(b) with flexibility for residents in a secure dementia care unit.
- (b) In addition to subsection (1) of this section, subsections (2) to (5) of this section of this administrative regulation shall apply to facilities licensed to operate as an ALC-BH or ALC-DC.
- (2) Therapeutic diets. If the facility provides therapeutic diets and the staff member responsible for food services is not a licensed dietician or certified nutritionist, the responsible staff person shall consult with a licensed dietician or certified nutritionist.
- (3) Menu planning.
- (a) Menus shall be planned in writing and rotated to avoid repetition.
- (b) An ~~ALC, ALC-BH,~~ or ALC-DC shall meet the nutritional needs of residents.
- (c) Meals shall correspond with the posted menu.
- (d) Menus shall be planned and posted one (1) week in advance.

- (e) If changes in the menu are necessary:
 - 1. Substitutions shall provide equal nutritive value;
 - 2. The changes shall be recorded on the menu; and
 - 3. Menus shall be kept on file for thirty (30) days.
- (4) Food preparation and storage.
 - (a) There shall be at least a three (3) day supply of food to prepare well-balanced, palatable meals.
 - (b) Food shall be prepared with consideration for any individual dietary requirement.
 - (c) Modified diets, nutrient concentrates, and supplements shall be given only on the written order of a **licensed health professional**~~physician~~.
 - (d) At least three (3) meals per day shall be served with not more than a fifteen (15) hour span between the evening meal and breakfast.
 - (e) At least two (2) hot meals daily shall be offered.
 - (f) Between-meal snacks, including an evening snack before bedtime shall be offered to all residents.
 - (g) Adjustments shall be made if medically contraindicated.
 - (h) Food shall be:
 - 1. Prepared by methods that conserve nutritive value, flavor, and appearance; and
 - 2. Served at the proper temperature and in a form to meet individual needs.
 - (i) A file of tested recipes, adjusted to appropriate yield, shall be maintained.
 - (j) Food shall be cut, chopped, or ground to meet individual needs.
 - (k) If a resident refuses food served, substitutes of equal nutritional value and complementary to the remainder of the meal shall be offered and recorded.
 - (l) All opened containers or leftover food items shall be covered and dated when refrigerated.
 - (m) Drinking water shall be readily available to the residents at all times.
 - (n) Food services shall be provided in accordance with 902 KAR 45:005.
- (5)
 - (a) Nothing in this administrative regulation shall be construed as taking precedence over the resident's right to make decisions regarding his or her eating and dining.
 - (b) Information about the resident's eating and dining preferences shall be included in the resident's service plan based on the resident's preferences.
 - (c) If the resident's eating and dining preferences have a potential health risk, staff shall inform the resident and the resident's designated contact person or legal representative.

Section 10. Employee Records and Requirements.~~[-Employee records.]~~

- (1) Each ALC, ALC-BH, or ALC-DC shall maintain a current record of each:
 - (a) Staff person employed by the facility directly or by contract; and
 - (b) Regularly scheduled volunteer providing **direct care** services.
- (2) The record **for each staff person** shall include the following:
 - (a) Evidence of current professional licensure, registration, or certification, if applicable;
 - (b) Documentation of orientation completed within thirty (30) days from the date of hire and annual training;
 - (c) Documentation of annual performance evaluations;
 - (d) Current job description, including qualifications, responsibilities, and identification of each staff person who provides supervision;
 - (e) Documentation of background checks in accordance with Section 14(1) of this administrative regulation; and
 - (f) Record of any health exams related to employment, including compliance with the tuberculosis testing requirements of 902 KAR 20:205.

(3) The record for each regularly scheduled volunteer shall include documentation of background checks in accordance with Section 14(1) of this administrative regulation.

(4) ~~(a)~~ Each ~~employee~~ record shall be retained for at least three (3) years after an employee or volunteer ceases to be employed by or provides services at the facility.

(5) ~~(b)~~ If a facility ceases operation, ~~employee~~ records shall be maintained for three (3) years after facility operations cease.

Section 11. Prevention and Control of Tuberculosis and Other Communicable Diseases.

(1) Each ALC, ALC-BH, and ALC-DC shall maintain written evidence of compliance with the screening and testing requirements of:

(a) 902 KAR 20:200, Tuberculosis (TB) testing for residents in long-term care settings; and

(b) 902 KAR 20:205, Tuberculosis (TB) testing for health care workers.

(2) An ALC, ALC-BH, and ALC-DC shall follow current requirements related to communicable diseases pursuant to KRS 194A.717(4).

(3) In accordance with KRS 194A.707(6), each ALC, ALC-BH, and ALC-DC may provide residents or their designated representatives with educational information or educational opportunities on influenza disease by September 1 of each year.

Section 12. Disaster Planning and Emergency Preparedness Plan.

(1) Each ALC, ALC-BH, and ALC-DC shall:

(a) Have a written emergency disaster plan that:

1. Contains a plan for evacuation, including the written policy required by Section 7(4)(c) of this administrative regulation and KRS 194A.717(5);

2. Addresses elements of sheltering in place or provides instructions for finding a safe location indoors and staying there until given an all clear or told to evacuate;

3. Identifies temporary relocation sites; and

4. Details staff assignments in the event of a disaster or an emergency;

(b) Post an emergency disaster plan prominently;

(c) Provide building emergency exit diagrams to all residents;

(d) Post emergency exit diagrams on each floor; and

(e) Have a written policy and procedure regarding missing tenant residents.

(2)

(a) Each ALC, ALC-BH, and ALC-DC shall:

1. Provide emergency and disaster training to all staff during the initial staff orientation and annually; and

2. Make emergency and disaster training available to residents annually.

(b) Staff who have not received emergency and disaster training shall be allowed to work only if trained staff are also working on site.

Section 13. Resident Records.

(1) Each ALC, ALC-BH, and ALC-DC shall maintain a record for each resident.

(2) Entries in the resident record shall be current, legible, permanently recorded, dated, and authenticated with the name and title of the staff person making the entry.

(3) Resident records, whether written or electronic, shall be protected against loss, tampering, or unauthorized disclosure.

(4) Each resident record shall include the following:

(a) Resident's name, date of birth, address, and telephone number;

(b) Name, address, and telephone number of the resident's legal representative or designated contact person;

(c) Names, addresses, and telephone numbers of the resident's health and medical service providers, if known;

- (d) Health information, including medical history, allergies, tuberculosis test results, vaccination information, and if the provider is managing medications, treatments, or therapies, documentation of the administration of all medications or delivery of treatments or therapy services;
 - (e) The resident's advance directives, if any;
 - (f) Copies of any health care directives, guardianships, powers of attorney, or conservatorships;
 - (g) The resident's current and previous functional needs assessments and service plans;
 - (h) All records of communications pertinent to the resident's services;
 - (i) Documentation of significant changes in the resident's status and actions taken in response to the needs of the resident, including reporting to the appropriate supervisor or **licensed** health ~~care~~ professional;
 - (j) Documentation of any incident or accident involving the resident and actions taken in response to the needs of the resident, including reporting to the appropriate supervisor or **licensed** health ~~care~~ professional;
 - (k) Documentation that services have been provided as identified in the service plan and according to any required orders received from the resident's health care practitioner;
 - (l) Documentation of administration of medications and delivery of therapeutic services;
 - (m) Documentation of all verbal prescription orders received by phone and signed by the authorized health **professional**~~care practitioner~~ within thirty (30) days;
 - (n) Documentation that the resident has received and reviewed the resident's rights;
 - (o) Documentation of complaints received and any resolution;
 - (p) Documentation of move-out or transfer to another setting, if applicable; and
 - (q) Other documentation relevant to the resident's services or status.
- (5) With the resident's knowledge and consent, if a resident is relocated to another facility or if care is transferred to another service provider, the ALC, ALC-BH, or ALC-DC shall convey to the new facility or provider the:
- (a) Resident's full name, date of birth, and insurance information;
 - (b) Name, telephone number, and address of the resident's designated contacts or legal representatives, if any;
 - (c) Resident's current documented diagnoses that are relevant to the services being provided;
 - (d) Resident's known allergies that are relevant to the services being provided;
 - (e) Name and telephone number of the resident's physician, if known, and the current physician orders that are relevant to the services being provided;
 - (f) All medication administration records and treatment sheets that are relevant to the services being provided;
 - (g) Most recent functional needs assessment; and
 - (h) Copies of health care directives, "do not resuscitate" orders, and any guardianship orders or powers of attorney.
- (6)
- (a) Following a resident's move-out or termination of services, an ALC, ALC-BH, or ALC-DC shall retain a resident's record for at least six (6) years.
 - (b) Arrangements shall be made for secure storage and retrieval of resident records if the facility ceases to operate.
- (7) Ownership.
- (a) Any medical records shall be the property of the ALC, ALC-BH, or ALC-DC.
 - (b) The original medical record shall not be removed except by court order.
 - (c) Copies of medical records or portions thereof may be used and disclosed in accordance with the requirements established in this administrative regulation.

(8) Confidentiality and Security: Use and Disclosure.

(a) The ALC, ALC-BH, or ALC-DC shall maintain the confidentiality and security of resident records in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 42 U.S.C. 1320d-2 to 1320d-8, and 45 C.F.R. Parts 160 and 164, as amended, including the security requirements mandated by subparts A and C of 45 C.F.R. Part 164, or as provided by applicable federal or state law.

(b) The ALC, ALC-BH, or ALC-DC may use and disclose resident records. Use and disclosure shall be as established or required by HIPAA, 42 U.S.C. 1320d-2 to 1320d-8, and 45 C.F.R. Parts 160 and 164, or as established in this administrative regulation.

(c) An ALC, ALC-BH, or ALC-DC may establish higher levels of confidentiality and security than those required by HIPAA, 42 U.S.C. 1320d-2 to 1320d-8, and 45 C.F.R. Parts 160 and 164.

Section 14. Staff Requirements.

(1) Background checks.

(a) All owners, ~~and~~ staff, **and regularly scheduled volunteers** in a position that involves providing direct care services to residents, **which may include access to the belongings, funds, or personal information of residents** shall:

1. Have a criminal record check performed pursuant to KRS 216.789(3);
2. In accordance with KRS 216.789(1), not have a criminal conviction or plea of guilty to a felony offense related to:
 - a. Theft;
 - b. Abuse or sale of illegal drugs;
 - c. Abuse, neglect, or exploitation of an adult; or
 - d. A sexual crime;
3. In accordance with KRS 216.789(2), not have a criminal conviction or plea of guilty to a misdemeanor offense related to abuse, neglect, or exploitation of an adult;
4. Not have a criminal conviction or plea of guilty to a felony or misdemeanor offense related to abuse, neglect, or exploitation of a child;
5. In accordance with KRS 209.032, not be listed on the caregiver misconduct registry established by 922 KAR 5:120; and
6. In accordance with KRS 216.532, not be listed on the nurse aide abuse registry established by 906 KAR 1:100.

(b) Staff in a position that involves providing direct care services to residents shall submit to a:

1. Criminal background check upon initial hire and no less than every two (2) years thereafter; and
2. Check of the following registries upon initial hire and annually thereafter:
 - a. Caregiver misconduct registry;
 - b. Nurse aide abuse registry; and
 - c. Central registry established by 922 KAR 1:470.

(c) An ALC, ALC-BH, or ALC-DC may use Kentucky's national background check program established by 906 KAR 1:190 to satisfy the background check requirements of paragraphs (a) and (b) of this subsection.

(d) In accordance with KRS 216.789(4), an ALC, ALC-BH, or ALC-DC may temporarily employ an applicant pending receipt of the results of a criminal record check performed upon initial hire.

(2) Licensed health professionals and nurses. ~~Except for a social model ALC,~~ A licensed health professional or nurse who provides services to residents of an ALC-BH or ALC-DC shall possess a current Kentucky license **or multistate licensure privilege** to practice **in Kentucky**.

(3) Staffing.

(a) In accordance with KRS 194A.717(1), staffing in an ALC, ALC-BH, or ALC-DC shall be sufficient in number and qualifications to meet the twenty-four (24) hour scheduled needs of each resident pursuant to the lease agreement, functional needs assessment, and service plan.

(b) In accordance with KRS 194A.717(2), at least one (1) staff person shall be awake and on-site at all times at each:

1. Licensed entity; or
2. Building on the same campus for two (2) or more buildings operated by the same licensee.

(c) The designated manager (director) of the facility shall meet the requirements of KRS 194A.717(3).

(4) Availability of nurse.

~~{(a)}~~ An ALC-BH and ALC-DC shall have a ~~{registered}~~ nurse readily available ~~{for consultation by staff performing delegated nursing tasks.}~~

~~{(b)}~~ ~~{The registered nurse shall be readily available}~~ in person, by telephone, or by other means of live, two-way communication to unlicensed ~~{the}~~ staff at times the staff is providing delegated nursing tasks ~~{services}~~.

(5) Delegation of assisted living services.

(a)

1. ~~{Except for a social model ALC,}~~ A nurse in an ALC-BH or ALC-DC ~~{registered nurse or licensed health professional}~~ may delegate tasks in accordance with 201 KAR 20:400.

2. A licensed health professional in an ALC-BH or ALC-DC may delegate tasks in accordance with the professional's ~~{practitioner's}~~ scope of practice standards only to those staff who possess the knowledge and skills consistent with the complexity of the tasks delegated.

(b) The ALC-BH or ALC-DC shall establish and implement a system to communicate up-to-date information to the ~~{registered}~~ nurse or appropriate licensed health professional regarding current available staff so the ~~{registered}~~ nurse or licensed health professional has sufficient information to determine the appropriateness of delegating tasks to meet individual resident needs and preferences.

(c) If the ~~{registered}~~ nurse or licensed health professional delegates tasks to unlicensed personnel, the ~~{registered}~~ nurse or health professional shall ensure that prior to the delegation the unlicensed staff person is trained in the proper methods to perform the tasks and demonstrates competence in performing the tasks.

(d) If an unlicensed staff person has not regularly performed the delegated assisted living task during the previous twenty-four (24) month period, the unlicensed staff person shall demonstrate competency in the task to the ~~{registered}~~ nurse or appropriate licensed health professional.

(e) The ~~{registered}~~ nurse or licensed health professional shall document delegated nursing or other assigned ~~{instructions for the delegated}~~ tasks in the resident's record.

(6) Supervision of staff providing non-health related services.

(a) Staff who provide only those assisted living services identified in KRS 194A.700(7)(a)-(f), (i) or (n) shall be supervised periodically to:

1. Verify that the work is being performed competently; and
2. Identify problems and solutions to address issues relating to the staff's ability to provide the services.

(b) The supervision of unlicensed personnel shall be done by staff who:

1. Have the authority, skills, and ability to provide the supervision of unlicensed personnel;

2. Can implement changes as needed; and
3. Can train staff.
- (c) Supervision may include~~includes~~:
 1. Direct observation of an unlicensed staff person while the unlicensed staff person is providing the services; and
 2. Indirect methods of gaining input such as gathering feedback from the resident.
- (d) Supervisory review of unlicensed staff shall be provided at a frequency based on the unlicensed staff person's knowledge, skills, and performance.
- (7) Supervision of staff providing delegated nursing or therapy tasks.
 - (a) An unlicensed staff person who performs:
 1. Delegated nursing tasks shall be supervised by a nurse pursuant to the requirements of 201 KAR 20:400, Section 4; or
 2. Therapy tasks shall be supervised by ~~a registered nurse or~~ an appropriate licensed health professional according to the facility's policy to:
 - a. ~~1.1~~ Verify that the work is being performed competently; and
 - b. ~~1.2~~ Identify problems and solutions related to the staff person's ability to perform the tasks.
 - (b) Supervision of an unlicensed staff person performing medication or treatment administration~~shall~~:
 1. Shall be provided by a ~~registered~~ nurse or appropriately licensed health professional; and
 2. May include observation of the staff person administering the medication or treatment and the interaction with the resident.
 - (c) The direct supervision of an unlicensed staff person performing a delegated task shall be provided the first time the staff person performs the delegated task and on an as needed basis thereafter based on performance.
- (8) Orientation and annual training.
 - (a) Prior to working independently with residents and within thirty (30) days from the date of hire, all staff and management shall receive orientation education that addresses the topics required by KRS 194A.719(1) with emphasis on those most applicable to the employee's assigned duties.
 - (b) All staff and management shall receive annual training in accordance with KRS 194A.719(2), which shall include in-service education regarding Alzheimer's disease and other types of dementia.

Section 15. Medication Management.

- (1) Medication management services.
 - (a) This section of this administrative regulation applies to facilities licensed to operate as an ALC-BH or ALC-DC.
 - (b) Medications or therapeutic services shall not be administered or provided to any resident except on the order of a licensed health care practitioner as authorized under the practitioner's scope of practice.
 - (c) Each facility subject to this section shall develop, implement, and maintain written medication management policies and procedures developed under the supervision and direction of a ~~registered~~ nurse, appropriate licensed health professional, or pharmacist consistent with scope of practice standards and guidelines.
 - (d) The policies and procedures shall address:
 1. Requesting and receiving prescriptions for medications;
 2. Preparing and giving medications;
 3. Verifying that prescription drugs are administered as prescribed;
 4. Documenting medication management activities;

5. Storage of medications, which shall include compliance with the following requirements:

- a. All medications shall be kept in a locked place;
- b. All medications requiring refrigeration shall be kept in a separate locked box in the refrigerator in the medication area; and
- c. Drugs for external use shall be stored separately from those administered by mouth or injection;

6. Monitoring and evaluating medication use;

7. Resolving medication errors;

8. Communicating with the prescriber, pharmacist, resident and if applicable, designated contact person or legal representative;

9. Disposing of unused medications; and

10. Educating residents and designated contacts or legal representatives about medications.

(e) If controlled substances are being managed, the policies and procedures shall identify how the facility ensures security and accountability for the overall management, control, and disposition of those substances in accordance with subsection (21) of this section.

(f) All resident medications shall be plainly labeled with the:

1. Resident's name;
2. Name of the drug;
3. Strength;
4. Name of the pharmacy;
5. Prescription number;
6. Date;
7. Prescriber's name; and
8. Caution statements and directions for use, unless a modified unit dose drug distribution system is used.

(2) Provision of medication management services. Prior to providing medication management services to a resident pursuant to orders from the resident's health care practitioner in accordance with KRS 194A.708(1)(d), the facility shall have a registered nurse or other licensed health professional~~prescribing practitioner shall~~ conduct an assessment that shall:

(a) Be face-to-face with the resident;

(b) Determine what medication management services will be provided and how the services will be provided;

(c) Include an identification and review of all medications the resident is known to be taking. The review and identification shall include:

1. Indications for medications;
2. Side effects;
3. Contraindications; and
4. Possible allergic or adverse reactions, and actions to address these issues;

(d) Identify interventions needed in the management of medications to prevent diversion of medication by the resident or others who may have access to the medications; and

(e) Provide instructions to the resident and designated contacts or legal representatives on interventions to prevent diversion of medications such as misuse, theft, or illegal or improper disposition of medications.

(3) Individualized medication monitoring and reassessment. The ALC-BH or ALC-DC shall reassess the resident's medication management services in accordance with subsection (2) of this section:

- (a) If the resident presents with symptoms or other issues that may be medication-related; and
- (b) No later than every twelve (12) months.
- (4) Resident refusal. The ALC-BH or ALC-DC shall:
 - (a) Document in the resident's record any refusal for an assessment for medication management;~~and~~
 - (b) Discuss ~~with the resident~~ the possible consequences of the resident's refusal with the:
 - 1. Resident;
 - 2. Resident's designated contact person or legal representative; or
 - 3. Both individuals identified by subparagraph 2. and 3. of this paragraph; and
 - (c) Document the discussion in the resident's record.
- (5) Individualized medication management plan.
 - (a) For each resident receiving medication management services, the ALC-BH or ALC-DC shall develop and maintain a current individualized medication management record for each resident based on the resident's assessment.
 - (b) The medication management record shall be updated if there is a change and contain:
 - 1. A statement describing the medication management services that will be provided to the resident;
 - 2. A description of storage of medications that:
 - a. Is based on the resident's needs and preferences;
 - b. Reduces risk of diversion; and
 - c. Is consistent with the manufacturer's directions;
 - 3. Documentation of specific instructions relating to the administration of medications to the resident;
 - 4. Identification of persons responsible for monitoring medication supplies and ensuring that medication refills are ordered on a timely basis;
 - 5. Identification of medication management tasks that may be delegated to unlicensed personnel;
 - 6. Procedures for staff to notify a ~~registered~~ nurse or appropriate licensed health professional if a problem arises with medication management services; and
 - 7. Any resident-specific requirements related to:
 - a. Documenting medication administration;
 - b. Verification that all medications are administered as prescribed; and
 - c. Monitoring of medication use to prevent possible complications or adverse reactions.
 - (c) Medication reconciliation shall be completed by a ~~registered~~ nurse, licensed health ~~professional~~~~care~~~~practitioner~~ acting within the ~~professional's~~~~practitioner's~~ scope of practice, or authorized prescriber for each resident receiving medication management services.
- (6) Administration of medication. A licensed health ~~care~~ professional may:
 - (a) Administer medications as authorized under the professional's scope of practice; or
 - (b) Delegate medication administration tasks in accordance with subsection (7) of this section.
- (7) Delegation of medication administration.
 - (a) Unlicensed personnel who meet the requirements of subparagraph 1. of this paragraph may only administer oral or topical medication or preloaded injectable insulin if delegated to them by a nurse or appropriate licensed health ~~care~~ professional. If medication administration is delegated to unlicensed personnel, the ALC-BH or ALC-DC shall ensure that the ~~registered~~ nurse or licensed health ~~care~~ professional has:

1. ~~{(a)}~~ Delegated medication administration to a staff person who:
 - a. Is a certified medication aide; or
 - b. Has~~{-}~~
 - ~~{1-}~~ successfully completed a:
 - (i) ~~{the Kentucky}~~ Medication aide training program accepted by the Kentucky Board of Nursing (KBN);
 - (ii) Skills competency evaluation; and
 2. ~~{Demonstrated the ability to competently follow the procedures;}~~
 - ~~{(b)}~~ ~~{Instructed the unlicensed personnel in the proper methods to administer oral or topical medications;}~~
 - ~~{(c)}~~ Specified, in writing, specific instructions for each resident and documented those instructions in the resident's records; and
 3. ~~{(d)}~~ Communicated with the unlicensed personnel about the individual needs of the resident.
- (b) The ALC-BH or ALC-DC shall ensure that a nurse or licensed health professional is readily available during times the unlicensed staff administers medications in accordance with Section 14(4) of this administrative regulation.**
- (8) Documentation of administration of medications.
 - (a) Each medication administered shall be documented in the resident's record.
 - (b) The documentation shall include the:
 1. Signature and title of the staff person who administered the medication;
 2. The medication name, dosage, date, and time administered; and
 3. Method and route of administration.
 - (c) The staff person shall document the:
 1. Reason why medication administration was not completed as prescribed, if applicable; and
 2. Any follow-up procedures that were provided to meet the resident's needs if medication was not administered as prescribed and in compliance with the resident's medication management plan.
 - (9) Documentation of medication setup. At the time of medication setup, the authorized health ~~professional~~~~{care practitioner}~~ shall document the following in the resident's record:
 - (a) Date of medication setup;
 - (b) Name of medication;
 - (c) Quantity of dose;
 - (d) Times to be administered;
 - (e) Route of administration; and
 - (f) Name of the staff person completing the medication setup.
 - (10) Medication management for residents who will be away from the facility.
 - (a) An ALC-BH or ALC-DC shall develop and implement policies and procedures for giving accurate and current medications to the resident for planned or unplanned times away from the facility according to the resident's individualized medication management plan.
 - (b) The policies and procedures shall state that:
 1. For planned time away, the medications shall be obtained from the pharmacy or set up by the ~~{registered}~~ nurse or authorized health ~~professional~~~~{care practitioner}~~;
 2. For unplanned time away, if the pharmacy is not able to provide the medications, a ~~{registered}~~ nurse or authorized health ~~professional~~~~{care practitioner}~~ shall provide medications in the amounts and dosages needed for the length of the anticipated absence, not to exceed seven (7) calendar days.
 - (c) The ALC-BH or ALC-DC shall:

1. Provide the resident with written information on medications, including any special instructions for administering or handling the medications;
 2. Place the medications in a medication container or containers appropriate to the provider's medication system; and
 3. Label the container or containers with the:
 - a. Resident's name; and
 - b. The dates and times that the medications are scheduled.
- (11) Over-the-counter drugs and dietary supplements not prescribed.
- (a) An ALC-BH or ALC-DC providing medication management services for over-the-counter drugs or dietary supplements shall retain those items in the original labeled container with directions for use prior to setting up for immediate or later administration.
- (b) The ALC-BH or ALC-DC shall verify that the medications are up to date and stored as appropriate.
- (12) Prescriptions. There shall be a current written or electronically recorded prescription for all prescribed medications that the ALC-BH or ALC-DC is managing for the resident.
- (13) Renewal of prescriptions. Prescriptions shall be renewed at least every twelve (12) months or more frequently as indicated by the assessment in subsection (2) of this section.
- (14) Verbal prescription orders. If an order is received by telephone, the order shall be:
- (a) Recorded in the resident's medication management record; and
- (b) Signed by the physician or health care practitioner as authorized under the practitioner's scope of practice within thirty (30) days.
- (15) Written or electronic prescription. At the time a written or electronic prescription is received, it shall be:
- (a) Communicated to the ~~registered~~ nurse in charge; and
- (b) Recorded or placed in the resident's record.
- (16) Medications provided by resident or family members. If a staff person becomes aware of any medications or dietary supplements that are being used by the resident and are not included in the assessment for medication management services, the staff person shall advise the ~~registered~~ nurse and document that in the resident record.
- (17) Storage of medications. Except for the storage of controlled substances that shall be kept under a double lock in accordance with subsection (21)(b) of this section, an ALC-BH or ALC-DC shall store all prescription medications in securely locked and substantially constructed compartments according to the manufacturer's directions and permit only authorized personnel to have access.
- (18) Prescription drugs. A prescription drug, prior to being set up for immediate or later administration, shall be kept in the original container in which it was dispensed by the pharmacy bearing the original prescription label with legible information including the expiration or beyond-use date of a time-dated drug.
- (19) Prohibitions. No prescription drug supply for one (1) resident may be used or saved for use by anyone other than the resident.
- (20) Disposition of medications.
- (a) Any current medications being managed by the ALC-BH or ALC-DC shall be provided to the resident if:
1. The resident's service plan ends; or
 2. Medication management services are no longer part of the service plan.
- (b) The ALC-BH or ALC-DC shall dispose of any medications remaining with the facility:
1. That are discontinued or expired; or
 2. Upon termination of the service plan or the resident's death.

(c) Upon disposition, the facility shall document in the resident's record the disposition of the medication, including:

1. The medication's name, strength, prescription number as applicable, and quantity;
2. How the medication was disposed of or to whom the medications were given;
3. Date of disposition; and
4. Names of staff and other individuals involved in the disposition.

(21) Controlled substances.

(a) Controlled substances. An ALC-BH or ALC-DC shall not keep any controlled substances or other habit forming drugs, hypodermic needles, or syringes except under the specific direction of a prescribing practitioner.

(b) Controlled substances shall be kept under double lock, for example, stored in a locked box in a locked cabinet, and keys or access codes to the locked box and locked cabinet shall be accessible to designated staff only.

(c) There shall be a controlled substances bound record book with numbered pages that includes:

1. Name of the resident;
2. Date, time, kind, dosage, and method of administration of each controlled substance;
3. Name of the practitioner who prescribed the medications; and
4. Name of the nurse who:
 - a. Administered the controlled substance; or
 - b. Supervised self-administration by a resident whose medical record includes a written determination from an appropriately authorized~~at~~ health professional~~care practitioner~~ that the resident is able to safely self-administer a controlled substance under supervision.

(d) An appropriately authorized ~~At~~ licensed health professional~~practitioner~~ with access to controlled substances shall be responsible for maintaining a recorded and signed:

1. Schedule II controlled substances count daily; and
2. Schedule III, IV, and V controlled substances count at least one (1) time per week.

(e) All expired or unused controlled substances shall be disposed of, or destroyed in accordance with 21 C.F.R. Part 1317 no later than thirty (30) days:

1. After expiration of the medication; or
2. From the date the medication was discontinued.

(f) If controlled substances are destroyed on-site:

1. The method of destruction shall render the drug unavailable and unusable;
2. The administrator or staff person designated by the administrator shall be responsible for destroying the controlled substances with at least one (1) witness present; and
3. A readily retrievable record of the destroyed controlled substances shall be maintained for a minimum of eighteen (18) months from the date of destruction and contain the:
 - a. Date of destruction;
 - b. Resident name;
 - c. Drug name;
 - d. Drug strength;
 - e. Quantity;
 - f. Method of destruction;
 - g. Name and signature of the person responsible for the destruction; and
 - h. Name of the witness.

(g) For purposes of this paragraph, an ALC-BH or ALC-DC shall be treated the same as a licensed personal care home that stores and administers controlled substances in

an emergency medication kit (EMK) in which case the facility shall comply with the same:

1. Requirement for licensed personnel established by 201 KAR 2:370, Section 2(4)(i);
2. Requirements for storage and administration established by 902 KAR 55:070, Section 2(2), (5), (7), (8), and (9); and
3. Limitation on the number and quantity of medications established by 902 KAR 55:070, Section 2(6).

(22) Emergency drugs for non-controlled substances in an EMK.

(a) For purposes of this paragraph, an ALC-BH or ALC-DC shall be treated the same as a licensed personal care home that stores and administers non-controlled substances in an EMK in which case the facility shall comply with the same:

1. Requirement for licensed personnel established by 201 KAR 2:370, Section 2(4)(i); and
2. Limitation on the number and quantity of medications established by 201 KAR 2:370, Section 2(4)(b).

(b) An ALC-BH or ALC-DC that stores and administers non-controlled substances from a long-term care facility (LTCF) drug stock shall comply with the limitation on the number and quantity of medications established by 201 KAR 2:370, Section 2(5)(b).

(23) Loss or spillage.

(a) An ALC-BH or ALC-DC shall develop and implement procedures to address loss or spillage of all controlled substances.

(b) The procedures shall require that if spillage of a controlled substance occurs, a notation shall be made in the resident's record explaining the spillage and the actions taken.

(c) The notation shall be signed by the person responsible for the spillage and include verification that any contaminated substance was disposed of.

(d) The procedures shall require that the ALC-BH or ALC-DC:

1. Investigate any known loss or unaccounted for prescription drugs;
2. Document the investigation in required records; and
3. Provide a copy of the detailed list of controlled substances lost, destroyed, or stolen to the Office of Inspector General:
 - a. Division of Audits and Investigations as soon as practical pursuant to KRS 218A.200(6); and
 - b. Division of Health Care.

Section 16. Assisted Living Communities with Dementia Care.

(1) An applicant for licensure as an ALC-DC shall provide services in a manner that is consistent with the requirements of KRS 194.7061(1) – (3).

(2) An ALC-DC shall comply with KRS 194A.7065 and KRS 216.595.

(3) The manager (director) of an ALC-DC shall complete ten (10) hours of annual dementia-specific training in the topics established by KRS 194A.7201(2).

(4) An ALC-DC shall:

- (a) Develop policies and procedures in accordance with KRS 194A.708(1); and
- (b) Provide a copy of the policies and procedures to the resident and the resident's designated contact person or legal representative at the time of move-in.

(5) An ALC-DC shall ensure that the facility complies with the staffing standards established by KRS 194A.7203, including the requirement for only dementia-trained staff to care for residents on its secured dementia unit unless a temporary emergency situation exists.

(6) An ALC-DC shall:

- (a) Provide all of the services listed in KRS 194A.7052(1);
 - (b) Evaluate each resident on its secured dementia unit for engagement in activities and develop an individualized activity plan pursuant to KRS 194A.7052(2) and (3);
 - (c) Provide a selection of daily structured and non-structured activities for residents on its secured dementia unit in accordance with KRS 194A.7052(4);
 - (d) Evaluate behavioral symptoms that negatively impact residents on its secured dementia unit and others in the facility and comply with the requirements of KRS 194A.7052(5);
 - (e) Offer support services to the families of residents on its secured dementia unit and others with significant relationships at least every six (6) months in accordance with KRS 194A.7052(6); and
 - (f) For dementia care units constructed after July 14, 2022, offer access to secured outdoor space in accordance with KRS 194A.7052(7).
- (7) In addition to the training requirements of Section 14(8) of this administrative regulation, an ALC-DC shall meet the training requirements of KRS 194A.7205 for direct care staff who work in the facility's secured dementia care unit.

Section 17. Violation of Standards. An ALC, ALC-BH, or ALC-DC shall be subject to any applicable enforcement actions authorized by KRS 194A.722 and 902 KAR 20:008, Sections 7 and 8 for violations of the standards established by this administrative regulation, KRS 194A.700—194A.729, 216.532, or 216.789.

Section 18. Denial and Revocation.

- (1) In addition to the reasons for denial or revocation of a license in accordance with 902 KAR 20:008, Section 8, the cabinet shall deny or revoke an ALC, ALC-BH, or ALC-DC license if it finds that:
- (a) There has been a substantial failure by the facility to comply with the provisions of:
 - 1. KRS 194A.700—194A.729, 216.532, or 216.789; or
 - 2. This administrative regulation;
 - (b) The facility permits, aids, or abets the commission of any illegal act in the provision of assisted living services;
 - (c) The facility performs any act detrimental to the health, safety, or welfare of a resident;
 - (d) The facility obtains licensure by fraud or misrepresentation, including a false statement of a material in fact in:
 - 1. The Application for License to Operate an Assisted Living Community; or
 - 2. Any records required by this administrative regulation;
 - (e) The facility denies a representative of the cabinet access to any part of the facility's books, records, files, employees, or residents;
 - (f) The facility interferes with or impedes the performance of the duties and responsibilities of the long-term care ombudsman;
 - (g) The facility interferes with or impedes a representative of the cabinet in the enforcement of this administrative regulation or fails to fully cooperate with a survey or investigation by the cabinet;
 - (h) The facility destroys or makes unavailable any records or other evidence relating to the facility's compliance with this administrative regulation;
 - (i) The facility refuses to initiate a background check or otherwise fails to comply with the requirements of KRS 216.789;
 - (j) The facility fails to timely pay any fines assessed by the cabinet;
 - (k) The facility violates any applicable building or safety codes as determined by the building code or safety code enforcement authority with jurisdiction;
 - (l) There have been repeated incidents in the facility of personnel performing services beyond their competency level;

- (m) The facility continues to operate beyond the scope of the facility's license after the timeframe specified for correction of the violation; or
- (n) An individual with a significant financial interest in the facility:
 - 1. Is convicted of a felony or gross misdemeanor that relates to the operation of the facility or directly affects resident safety or care; or
 - 2. Had the application returned in accordance with Section 3(4) of this administrative regulation.
- (2) The cabinet shall follow the notification requirements of 902 KAR 20:008, Section 8(2) and (3) for denial or revocation.
- (3) In accordance with KRS 216B.105(2), the denial or revocation shall become final and conclusive thirty (30) days after notice is given, unless the applicant or licensee files a request in writing for a hearing with the cabinet within thirty (30) days after the date of the notice.

Section 19. Incorporation by Reference.

- (1) The following material is incorporated by reference:
 - (a) Form OIG – 20:480, "Application for Licensure to Operate an Assisted Living Community", November 2022 edition; and
 - (b) Form OIG – 20:480-A, "Functional Needs Assessment", **March 2023**~~November 2022~~ edition.
- (2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Office of Inspector General, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m. This material may also be viewed on the Office of Inspector General's Web site at: <https://chfs.ky.gov/agencies/os/oig/dhc/Pages/ltcapplications.aspx>.

ADAM MATHER, Inspector General
ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: March 8, 2023

FILED WITH LRC: March 15, 2023 at 8:00 a.m.

CONTACT PERSON: Krista Quarles, Policy Specialist, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person:Krista Quarles

(1) Provide a brief summary of:

(a) What this administrative regulation does:

This new administrative regulation establishes the minimum licensure requirements for the operation of social model assisted living communities (ALC), health care model assisted living communities that provide basic health and health-related services (ALC-BH), and assisted living communities with a secured dementia care unit (ALC-DC).

(b) The necessity of this administrative regulation:

This new administrative regulation is necessary to comply with the passage of SB 11 during the 2022 regular session.

(c) How this administrative regulation conforms to the content of the authorizing statutes:

This new administrative regulation conforms to the content of KRS 194A.700—194A.729 by establishing an initial and re-licensure review process. This new administrative regulation also conforms to the content of KRS 216B.042(1) by establishing the licensure standards and procedures to ensure safe, adequate, and efficient health facilities which is defined by KRS 216B.015(13) to include assisted living communities.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:

This new administrative regulation assists in the effective administration of KRS 194A.700—194A.729 by establishing minimum licensure requirements for the operation of social model ALCs, ALCs-BH, and ALCs-DC.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation:

In response to comments received during the public comment period, this amended after comments regulation includes the following changes: Adds “immediate family member”, “licensed health professional”, “nurse”, “nursing task” and “volunteer” to Section 1, Definitions. Clarifies that reports of abuse, neglect, or exploitation must be made to the Office of Inspector General and Department for Community Based Services. Clarifies that the delegation of nursing tasks and the supervision of unlicensed personnel performing delegated tasks in an ALC-BH or ALC-DC must be in compliance with 201 KAR 20:400. Adds an exemption from the prohibition against being a contact person or legal representative only if a staff person is an “immediate family member” of the resident. Clarifies that social model ALCs must continue to comply with the current requirements for dietary services in accordance with KRS 194A.703(2) and KRS 194A.705(1)(b) while ALCs-BH and ALCs-DC must comply with the remaining subsections of Section 9, Dietary services, which mirror the same requirements established by the PCH regulation, 902 KAR 20:036, Section 4(3)(c) for dietary services. Replaces “physician” with “licensed health professional” in Section 9(4)(c) to align with KRS 194A.700(7)(f). Clarifies that a record shall be maintained for each regularly scheduled volunteer and shall include documentation of a background check. Clarifies that employees with access to residents’ belongings, funds, or personal information are subject to the same

background checks required of direct care staff. Replaces all references to “health care professional” with “licensed health professional” as newly defined in Section 1. Replaces all references to “registered nurse” with “nurse” so that a licensed practical nurse (LPN) who provides services pursuant to KRS 194A.700(7)(g) in an ALC-BH or ALC-DC may delegate nursing tasks. Clarifies that a nurse in an ALC-BH or ALC-DC must be readily available in person, by telephone, or by other means to unlicensed staff at times the staff is providing delegated nursing tasks; deletes the requirement for a registered nurse to be available for consultation by staff performing delegated nursing tasks. Replaces the requirement for a nurse or licensed health professional in an ALC-BH or ALC-DC to document instructions for the delegated tasks in the resident’s record with a requirement for the nurse or licensed health professional to document delegated tasks in the resident’s record. Clarifies that the nurse or other licensed professional in an ALC-BH or ALC-DC shall be responsible for conducting a face-to-face assessment with the resident prior to providing medication management services. Clarifies that an ALC-BH or ALC-DC shall discuss the possible consequences of a resident’s refusal of an assessment for medication management with the resident, resident’s designated contact person or legal representative, or both. Clarifies that unlicensed staff who administer medications in an ALC-BH or ALC-DC under the delegation of a nurse must be: (1) a certified medication aide; or (2) have successfully completed a medication aide training program accepted by KBN and a skills competency evaluation. This change assures that unlicensed personnel are not limited solely to the Kentucky medication aide training program offered by the Kentucky Community and Technical College System. The use of properly trained and competent medication aides leads to fewer errors with drug use and medication administration, thereby enhancing liability protections for the facility and helping ensure fewer negative outcomes for residents. Allows certified medication aides in an ALC-BH or ALC-DC to administer preloaded injectable insulin in addition to oral or topical medications. Makes changes to the Functional Needs Assessment as described under the Summary of Material Incorporated by Reference.

(b) The necessity of the amendment to this administrative regulation:

This amended after comments regulation is necessary to address issues brought forth during the public comment period.

(c) How the amendment conforms to the content of the authorizing statutes:

This amended after comments regulation conforms to the content of KRS 194A.700 -194A.729 by establishing an initial and re-licensure review process. This amended after comments regulation also conforms to the content of KRS 216B.042(1) by establishing the licensure standards and procedures to ensure safe, adequate, and efficient health facilities which is defined by KRS 216B.015(13) to include assisted living communities.

(d) How the amendment will assist in the effective administration of the statutes:

This amended after comments regulation assists in the effective administration of KRS 194A.700 - 194A.729 by establishing minimum licensure requirements for the operation of social model ALCs, ALCs-BH, and ALCs-DC.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:

This administrative regulation affects ALCs. There are approximately 114 ALCs certified by the Department for Aging and Independent Living that will convert to licensed facilities regulated by the Office of Inspector General after adoption of this administrative regulation.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment:

In accordance with SB 11 and this administrative regulation, entities that convert their certification status or otherwise seek licensure as an ALC, ALC-BH, or ALC-DC will be required to submit an initial and annual renewal application to the cabinet with accompanying documentation. They will have to comply with the minimum licensure standards established by KRS 194A.700—194A.729 and this administrative regulation.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):

This administrative regulation was promulgated in accordance with the passage of SB 11, a measure brought forward by Kentucky's three long-term care associations.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3):

In accordance with the passage of SB 11 during the 2022 regular session, this administrative regulation will replace the current structure of certification of ALCs, which are currently prohibited from providing health services, with a framework that will allow ALCs to seek licensure to provide basic health and health-related services, including dementia care services. The overall goal of converting the current "social model" to a "health care model" will allow more seniors who reside in assisted living communities to age in place to the extent that basic health and health-related services are needed, which may also include dementia care services.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially:

The OIG anticipates an estimated cost of approximately \$352,000 to cover four (4) new staff positions that will be needed to absorb the workload associated with inspecting and monitoring licensed assisted living communities.

(b) On a continuing basis:

The OIG anticipates an estimated ongoing cost of approximately \$352,000 to cover the four (4) staff positions necessary to inspect and monitor licensed assisted living communities.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation:

State general funds and agency monies will be used to implement and enforce this new administrative regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment:

ALCs are currently subject to the fee schedule established by 910 KAR 1:240, Section 2(1)(e) for initial certification and Section 3(2)(c) for annual renewal. This new administrative regulation retains the same fee schedule for ALCs and therefore does not increase fees.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

This new administrative regulation establishes fees as authorized by KRS 194A.707(9) and retains the same fee structure as currently established by 910 KAR 1:240.

(9) TIERING: Is tiering applied?

Tiering is used because entities may seek licensure as a social model assisted living community, health care model assisted living community, or as an assisted living community with a secured dementia care unit defined by KRS 194A.700(6).

FISCAL NOTE

(1) What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation?

This administrative regulation impacts assisted living communities (ALC), apartment-style personal care homes that convert to ALC licensure, and the Cabinet for Health and Family Services, Office of Inspector General.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation.

KRS 194A.707(1) and (9), 216B.042(1)

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year?

Revenue is based on the number of licensed ALCs subject to the following fee schedule: ? Revenue is based on the number of licensed ALCs subject to the following fee schedule: Number of Units: <25, Rate: \$500 + \$40 per unit; Number of Units: 25-49, Rate: \$1,000 + \$40 per unit; Number of Units: 50-74, Rate: \$1,500 + \$40 per unit; Number of Units: 75-99, Rate: \$1,750 + \$40 per unit; Number of Units: 110 or more, Rate: \$2,000 + \$40 per unit.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years?

Ongoing revenue is based on the number of licensed ALCs subject to the above fee schedule.

(c) How much will it cost to administer this program for the first year?

The OIG anticipates an estimated cost of approximately \$352,000 to cover four (4) new staff positions that are needed to absorb the workload associated with inspecting and monitoring licensed ALCs during the first year.

(d) How much will it cost to administer this program for subsequent years?

The OIG anticipates an estimated ongoing cost of approximately \$352,000 to cover the four (4) staff positions necessary to inspect and monitor licensed ALCs.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year?

This administrative regulation will not generate cost savings for regulated entities during the first year.

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years?

This administrative regulation will not generate cost savings for regulated entities during subsequent years.

(c) How much will it cost the regulated entities for the first year?

This administrative regulation imposes no additional costs on regulated entities.

(d) How much will it cost the regulated entities for subsequent years?

This administrative regulation imposes no additional costs on regulated entities during subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Cost Savings (+/-):

Expenditures (+/-):

Other Explanation:

(5) Explain whether this administrative regulation will have a major economic impact, as defined below.

"Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars (\$500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)] The annual licensure fees paid by the roughly 114 assisted living communities is not anticipated to exceed \$500,000. Therefore, this new administrative regulation is not expected to have a major economic impact on the regulated entities.

FEDERAL MANDATE ANALYSIS COMPARISON

(1) Federal statute or regulation constituting the federal mandate.

21 C.F.R. Part 1317, 45 C.F.R. Parts 160, 164, 42 U.S.C. 1320d-2–1320d-8

(2) State compliance standards.

KRS 194A.707(1) and (9), 216B.042(1)

(3) Minimum or uniform standards contained in the federal mandate.

21 C.F.R. Part 1317, 45 C.F.R. Parts 160, 164, 42 U.S.C. 1320d-2–1320d-8

(4) Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate?

This administrative regulation does not impose requirements that are stricter than federal laws or regulations.

(5) Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements.

Not applicable.