

**CABINET FOR HEALTH AND FAMILY SERVICES**  
**Office of Inspector General**  
**Division of Health Care**  
**(Amendment)**

**902 KAR 20:036. Operation and services; personal care homes.**

RELATES TO: KRS 194A.700(1), ~~(2), (15), (26), 194A.705(2)(c), (9), (11),~~ 202A.011(12), 209.030, 209.032, 216.510 – 216.525, 216.530, 216.532, 216.555 to 216.567, 216.570-216.597, 216.765, 216.785-216.793, 216.597, 216A.080, 216B.010, ~~216B.130,~~ 216B.040, 216B.042, 216B.045-216B.130, 216B.990, 310.021, 310.031, 314.011(3), 21 C.F.R. Part 1317

STATUTORY AUTHORITY: KRS 216B.042, 216.597(7)(a).

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.042(1) requires the Cabinet for Health and Family Services 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. KRS 216.597(7)(a) requires the cabinet to promulgate administrative regulations related to licensure and relicensure of personal care homes (PCHs) and specialized personal care homes (SPHCs). This administrative regulation establishes minimum licensure requirements for the operation of and services provided by personal care homes, including specialized personal care homes.

Section 1. Definitions.

- (1) "Activities of daily living" or "ADL" is defined by KRS 194A.700(1).
- (2) "Administrator" means an individual who:
  - (a)
    1. Has a license to practice long-term care administration pursuant to KRS 216A.080; or
    2. Has a high school diploma, a general equivalency diploma (GED), or qualifying documentation from a comparable educational entity; and
  - (b) Is age twenty-one (21) or older.
- (3) "Ambulatory" is defined by KRS 216.597(2)(b) as having the same meaning as "ambulatory" as defined in KRS 194A.700(2)~~[means able to walk without assistance]~~.
- (4) "Certified nutritionist" means a health care professional who is certified pursuant to KRS 310.031.
- (5) "Instrumental activities of daily living" or "IADL" is defined by KRS 194A.700(15)~~(9)~~.
- (6) "Licensed dietician" means a health care professional who is licensed pursuant to KRS 310.021.
- (7) "Mobile nonambulatory" means unable to walk without assistance, but able to move from place to place with the use of a device including walkers, crutches, wheelchairs or other assistive medical devices~~[is defined by KRS 194A.700(11)]~~ and includes the ability to:
  - (a) Self exit the building; and
  - (b) Transfer independently or with minimal assistance from bed-to-chair.
- (8) "Nonambulatory" means unable to walk without assistance.
- (9) "Nonmobile" means unable to move from place to place.
- (10) "Nurse" is defined by KRS 314.011(3).
- (11) "Personal care home" or "PCH" is defined by KRS 216.597(1)(b)~~[means an establishment located in a permanent building that has resident beds and provides:]~~  
~~[(a)] [Supervision of residents;]~~

- ~~{(b)} [Basic health and health-related services;]~~
- ~~{(c)} [Personal care services;]~~
- ~~{(d)} [Residential care services; and]~~
- ~~{(e)} [Social and recreational activities].~~

~~(12) {(11)}~~ "Qualified mental health professional" or "QMHP" is defined by KRS 202A.011(12).

~~(13) {(12)}~~ "Restraint" means any pharmaceutical agent or physical or mechanical device used to restrict the movement of a portion of a patient's body.

~~(14) {(13)}~~ "Serious mental illness" or "SMI" means a mental illness or disorder (but not a primary diagnosis of Alzheimer's disease or dementia), that is described in the Diagnostic and Statistical Manual of Mental Disorders (DSM), 5th Edition, or the DSM currently in use, that impairs or impedes functioning in one (1) or more major areas of living and is unlikely to improve without treatment, services, or supports.

~~(15) {(14)}~~ "Specialized personal care home" or "SPCH" is defined by KRS 216.597(1)(c) ~~{means a personal care home that:}~~

~~{(a)} [Participates in the mental illness or intellectual disability supplement program pursuant to 921 KAR 2:015, Section 13; or]~~

~~{(b)} [Serves residents with thirty-five (35) percent or more having an SMI].~~

~~(16)~~ "Temporary condition" is defined by KRS 194A.700(26) in accordance with KRS 216.597(4).

~~(17)~~ "PRN" is defined as medications administrated as needed.

## Section 2. Licensure Application and On-site Visits.

(1) Upon approval of certificate of need followed by approval of plans and specifications submitted in accordance with 902 KAR 20:031, an applicant for a provisional license as a PCH or SPCH shall submit the following to the Office of Inspector General:

(a) A completed Application for License to Operate a Long Term Care Facility incorporated by reference in 902 KAR 20:008, Section 9(1)(f) accompanied by the licensure fee established by 902 KAR 20:008, Section 3(2)(g);

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

(c) A copy of the applicant's compliance history for any other care facility the applicant operates, including a copy of all enforcement actions issued by the regulatory agency against the care facility, such as violations, fines, or negative action against the facility's license during the seven (7) year period prior to application for a provisional license.

(2) A licensed PCH or SPCH shall comply with the annual renewal process established by 902 KAR 20:008, Section 2(14)(b).

(3) On-site inspections shall be conducted in accordance with the survey intervals established by KRS 216.597(7)(c).

(4) 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 a PCH or SPCH more often, if necessary.

(5) A PCH or SPCH shall comply with the:

(a) Inspection requirements of 902 KAR 20:008, Section 2(12)(b) and (c);

(b) Procedures for correcting violations established by 902 KAR 20:008, Section 2(13); and

(c) Civil monetary penalties established by KRS 216.555 to 216.567.

## Section 3. Scope of Operations and Services.

(1) A resident in a PCH or SPCH shall:

(a) Be admitted in accordance with KRS 216.765;

(b) Be ambulatory or mobile nonambulatory, unless the facility elects to provide services in accordance with KRS 216.597(4) to a resident who is deemed to have a

temporary condition;

(c) Be able to manage most of the activities of daily living; and

(d) Have care needs that do not exceed the capability of the PCH or SPCH.

(2) An individual who is nonambulatory or nonmobile shall not be eligible for residence in a PCH or SPCH pursuant to KRS 216.597(3).

Section 4. ~~[Section 3.]~~ Administration and Operation.

(1) Licensee. The licensee shall be legally responsible for:

(a) The operation of the PCH or SPCH;

(b) Compliance with federal, state, and local laws and administrative regulations pertaining to the operation of the facility;

(c) The development and implementation of policies related to administration and operation of the facility; ~~and~~

(d) If the licensee is ~~a~~an SPCH, the development and implementation of written transition procedures to ensure cooperation with an individual or entity that assists with transitioning residents with an SMI to community living arrangements; and

(e) If the licensee is an SPCH, access to confidential and secure telehealth services unless access is impossible to provide due to a lack of:

1. Broadband service; or

2. An appropriate physical space for residents.

(2) Administrator.

(a) The administrator shall:

1. Be responsible for the day-to-day operation of the PCH or SPCH; and

2. Designate one (1) or more staff to act on behalf of the administrator or to perform the administrator's responsibilities in the administrator's absence.

(b) Each SPCH shall ensure that the administrator completes the mental illness or intellectual disability training workshop established by 921 KAR 2:015, Section 14, within six (6) months of hire ~~[from the most recent effective date of this administrative regulation]~~ and every two (2) years thereafter.

(3) Admission.

(a) A PCH or SPCH shall not care or be responsible for the care of more residents than the capacity indicated on the license.

(b) Upon admission, a PCH or SPCH shall provide the resident and a responsible member of the resident's family or other designated representative with written information regarding the facility's policies, including:

1. Services offered and charges;

2. The right to arrange for additional services under direct contract or arrangement with an outside party pursuant to KRS 216.597(5) if permitted by the policies of the PCH or SPCH;

3. The right to visitation with family and friends, subject to visiting rules and hours established by the facility; and

4. ~~[3.]~~ Meal services.

(c) Prior to admission, each resident shall have a complete medical examination in accordance with KRS 216.765.

(d) ~~[No later than three (3) months from the most recent effective date of this administrative regulation, a PCH or SPCH shall complete the SMI Screening Form for each current resident.]~~ Upon admission, a PCH or SPCH shall complete the SMI Screening Form for each new or returning resident.

(4) Patient rights. Patient rights shall be provided for pursuant to KRS 216.510 to 216.525.

(5) Adult protection. PCHs and SPCHs shall have written policies that assure the reporting of allegations of abuse, neglect, or exploitation of adults pursuant to KRS

209.030, including evidence that all allegations of abuse, neglect, or exploitation shall be thoroughly investigated internally to prevent further potential abuse while the investigation is in progress.

(6) Emergency evacuation. Each PCH and SPCH shall have a written policy in accordance with KRS 216.597(6)(c) that describes 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.

(7) Nursing tasks. If nursing tasks are delegated, each PCH or SPCH shall have a written policy regarding the supervision of unlicensed personnel performing delegated tasks, including how the facility ensures compliance with the supervision requirements of 201 KAR 20:400, Section 4.

(8) Transfer and discharge.

(a) PCHs and SPCHs shall:

1. Comply with the requirements of 900 KAR 2:050 upon transferring or discharging a resident; and
2. Have written transfer procedures and agreements for the transfer of residents to a higher intensity level of care, if indicated.

(b) A PCH or SPCH that does not have a transfer agreement in effect, but has attempted in good faith to enter into an agreement shall be considered to be in compliance with the requirements of paragraph (a)2. of this subsection.

(c) The transfer procedures and agreements shall:

1. Specify the responsibilities each party assumes in the transfer of residents;
2. Establish responsibility for notifying the other party of an impending transfer; and
3. Arrange for safe transportation and transfer of files.

(d) The administrator shall initiate a transfer through the resident's physician or appropriate agencies if the resident's condition is not within the scope of services of the PCH or SPCH.

(e) PCH or SPCH resident records.

1. If a resident transfers to another health care facility, a current summary of the resident's medical record shall accompany the resident.
2. If a resident transfers to another level of care within the same facility, a copy of the resident's record or current summary of the resident's medical record shall accompany the resident.
3. If a resident transitions into a community living setting, a current summary of, or a copy of the resident's records shall be provided to the resident and the resident's guardian.

(9) ~~(7)~~ Tuberculosis Testing.

(a) All employees of a PCH or SPCH shall be screened and tested for tuberculosis in accordance with 902 KAR 20:205.

(b) Residents of a PCH or SPCH shall be screened and tested in accordance with 902 KAR 20:200.

(10) ~~(8)~~ Personnel.

(a) In accordance with KRS 216.532, a PCH or SPCH shall not employ or be operated by an individual who is listed on the nurse aide and home health aide abuse registry established by 906 KAR 1:100.

(b) In accordance with KRS 209.032, a PCH or SPCH shall not employ or be operated by an individual who is listed on the caregiver misconduct registry established by 922 KAR 5:120.

(c) A PCH or SPCH shall obtain a criminal record check on each applicant for initial employment in accordance with KRS 216.789 and 216.793.

(d) Current employee records shall be maintained on each staff member and contain:

1. Name and address;
  2. Verification of all training and experience, including evidence of current licensure, registration, or certification, if applicable;
  3. Employee health records;
  4. Annual performance evaluations; and
  5. Documentation of compliance with the background check requirements of paragraphs (a) through (c) of this subsection.
- (e) Each employee shall be of an age in conformity with state laws.
- (f) An employee who contracts a communicable or an infectious disease shall:
1. Be immediately excluded from work; and
  2. Remain off work until cleared as noninfectious by a health care practitioner acting within the practitioner's scope of practice.
- (g) Each dietary staff member shall wear a hair net.
- (h) In-service training.
1. Each PCH or SPCH employee shall receive orientation and annual in-service training that corresponds with the staff member's job duties.
  2. Documentation of orientation and in-service training shall be maintained in the employee's record and shall include:
    - a. Name of the individual or individuals who provided the training;
    - b. Date and number of hours the training was given; and
    - c. A summary of the training program's content.
  3. In-service training shall include:
    - a. Policies regarding the responsibilities of specific job duties;
    - b. Services provided by the facility;
    - c. Recordkeeping procedures;
    - d. Procedures for the reporting of cases of adult abuse, neglect, or exploitation pursuant to KRS 209.030;
    - e. Resident rights established by KRS 216.510 to 216.525;
    - f. Adult learning principles and methods for assisting residents to achieve maximum abilities in ADLs and IADLs;
    - g. Procedures for the proper application of emergency manual restraints;
    - h. Procedures for maintaining a clean, healthful, and pleasant environment;
    - i. The aging process;
    - j. The emotional problems of illness;
    - k. Use of medication; and
    - l. Therapeutic diets.
  4. Each SPCH shall ensure that at least one (1) direct care staff member in addition to the administrator completes the mental illness or intellectual disability training workshop established by 921 KAR 2:015, Section 14, within six (6) months of hire~~[from the most recent effective date of this administrative regulation]~~ and every two (2) years thereafter. An SPCH shall employ at least one (1) direct care staff member who has received the training.
- (i) Staffing requirements.
1. The number of personnel required shall be based on:
    - a. The number of patients; and
    - b. Amount and kind of personal care, health care, and supervision needed to meet the needs of the residents.
  2. The administrator shall designate one (1) or more staff members to be responsible for:
    - a. Recordkeeping;
    - b. Basic health and health related services; and
    - c. Activity services.

3. Each PCH or SPCH shall have a full-time staff member who shall be:
  - a. Responsible for the total food service operation of the facility; and
  - b. On duty a minimum of thirty-five (35) hours each week.
4. In accordance with KRS 216.597(6)(a) and (b):
  - a. Staffing in a PCH or SPCH shall be sufficient in number and qualifications to meet the twenty-four (24) hour scheduled needs of each resident; and
  - b. At least ~~[ensure that sufficient staff, but no less than]~~ one (1) staff member shall be awake and on-site at all times at each licensed facility.~~[on duty on each floor in the facility at all times].~~

(11) ~~(9)~~ Medical records.

(a) The PCH or SPCH administrator or staff member in charge of medical records shall assure that a complete medical record is kept for each resident with all entries current, dated, and signed.

(b) Each record shall include:

1. Identification information, including:
  - a. Resident's name;
  - b. Social Security, Medicare, and Medical Assistance identification number (if appropriate);
  - c. Marital status;
  - d. Birthdate;
  - e. Age;
  - f. Sex;
  - g. Home address;
  - h. Religion and personal clergyman, if any (with consent of the resident);
  - i. Attending physician, health care practitioner acting within the practitioner's scope of practice, QMHP, dentist, and podiatrist, if any, and address and phone number for each;
  - j. Next of kin or responsible person, address, and telephone number;
  - k. Date of admission and discharge;
  - l. If the resident is discharged, transferred, or transitioned to a community living arrangement, a copy of the summary of resident's records; and
  - m. Monthly recording of the resident's weight;
2. If admitted from another facility, a discharge summary or transfer summary;
3. Admitting medical evaluation;
4. Report by the physician or health care practitioner acting within the practitioner's scope of practice, documenting completion of an annual medical evaluation of each resident;
5. Physician, health care practitioner, or QMHP progress notes indicating any changes in the resident's condition, documented at the time of each visit by the physician, health care practitioner, QMHP, or consultant;
6. Orders for medication or therapeutic services;
7. Nurses' or staff notes indicating any changes in the resident's condition as changes occur;
8. Documentation of any accident, injury, illness, medication error, or drug reaction impacting the resident;
9. Documentation of social services, dental, laboratory, x-ray, or reports from consultants or therapists if the resident receives any of these services;
10. Medication and treatment sheets, including all medications, treatments, and special procedures performed for that resident, with the date and time of each service documented and initialed by the individual rendering treatment or administering medication;

11. Documentation of the use of an emergency manual restraint for that resident, including justification for why the procedure was used;
12. Documentation of the resident's discharge, transfer, or transition destination, if applicable;~~and~~
13. Copy of a completed SMI Screening Form for each PCH or SPCH resident; and
14. Monthly documentation of ADL and IADL skills instruction provided to, or made available and refused by, the resident if the resident is an SPCH resident who is transitioning to living independently in the community pursuant to 908 KAR 2:065.

(12) ~~(10)~~ Retention of records. After death or discharge, the completed medical record shall be placed in an inactive file and retained for at least six (6) years.

#### Section 5. ~~[Section 4.]~~ Provision of Services.

(1) Basic health and health related services.

(a) A PCH or SPCH shall provide basic health and health related services, including:

1. Supervision and monitoring of the resident to assure that the resident's health care needs are met;
2. Supervision of self-administration of medications;
3. Storage and control of medications; and
4. Arranging for therapeutic services ordered by the resident's health care practitioner, if the services are not available in the facility.

(b) For a PCH or SPCH, the administrator or staff person designated by the administrator shall, relating to the provision of basic health and health-related services:

1. Be responsible for obtaining medical care promptly in response to an accident, injury, or acute illness of any resident; and
2. Document any accident, injury, illness, incident, medication error, or drug reaction in the resident's medical record.

(c) Medications or therapeutic services shall not be administered or provided to any resident, except on the order of a licensed physician or other health care practitioner as authorized under the practitioner's scope of practice.

(d) If medication administration is delegated in accordance with 201 KAR 20:700, the PCH or SPCH shall have a nurse readily available in person, by telephone, or by other means of live, two-way communication to unlicensed staff at the times the staff is performing delegated nursing tasks.

(e) A PCH or SPCH may allow an unlicensed staff person to administer medication in accordance with KRS 194A.705(2)(c) and 201 KAR 20:700 as follows:

1. Medication administration is delegated to the unlicensed staff person by an available nurse;
2. If administration of oral or topical medication is delegated, the unlicensed staff person shall have a:
  - a. Certified medication aide (CMA) I credential from a training and skills competency evaluation program approved by the Kentucky Board of Nursing (KBN); or
  - b. Kentucky medication aide (KMA) credential from the Kentucky Community and Technical College System (KCTCS); and
3. If administration of a preloaded insulin injection is delegated, the unlicensed staff person shall have a CMA II credential from a training and skills competency evaluation program approved by KBN.

(f)

1. Unlicensed staff who administer oral or topical medications to residents of an SPCH shall comply with the medication aide requirements of paragraph (e) of this subsection no later than upon adoption of increased funding under the Mental Illness

or Intellectual Disability (MI/ID) Supplement Program established by 921 KAR 2:015, Section 13.

2. Unlicensed staff shall not administer a preloaded insulin injection under the delegation of a nurse to a PCH or SPCH resident prior to obtaining the CMA II credential.

(g) Administration of all medications and delivery of therapeutic services shall be recorded in the resident's medical record.

(h) ~~{(e)}~~ If an order is received by telephone, the order shall be:

1. Recorded in the resident's medical record; and
2. Signed by the physician or other health care practitioner as authorized under the practitioner's scope of practice within fourteen (14) days.

(i) ~~{(f)}~~

1. The administrator or staff person designated by the administrator shall make a written report of any incident or accident involving a:

- a. Resident, including a medication error or drug reaction;
- b. Visitor; or
- c. Staff member.

2. The report shall:

- a. Identify any staff member who might have been witness to the incident; and
- b. Be filed in an incident file.

(j) ~~{(g)}~~

1. Controlled substances and medication administration. A PCH or SPCH shall not keep any controlled substances or other habit forming drugs, hypodermic needles, or syringes except under the specific direction of a prescribing practitioner.

2. 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.

3. A nurse may delegate administration of a regularly scheduled or PRN controlled substance to a CMA if the medication has been prescribed and labeled in a container for a specific resident.

4. There shall be a controlled substances bound record book with numbered pages that includes:

- a. Name of the resident;
- b. Date, time, kind, dosage, and method of administration of each controlled substance;
- c. Name of the practitioner who prescribed the medications; and
- d. Name of the:

(i) Nurse or CMA who administered the controlled substance; or

(ii) Staff member who provided assistance with or supervised self-administration by a resident whose medical record includes a written determination from a health care practitioner that the resident is able to safely self-administer a controlled substance with assistance or under supervision.

5. ~~{4}~~ A staff member with access to controlled substances shall be responsible for maintaining a recorded and signed:

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

6. ~~{5}~~ 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:

- a. After expiration of the medication; or
- b. From the date the medication was discontinued.

7. ~~{6}~~ If controlled substances are destroyed on-site:

- a. The method of destruction shall render the drug unavailable and unusable;
- b. 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
- c. 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:
  - (i) Date of destruction;
  - (ii) Resident name;
  - (iii) Drug name;
  - (iv) Drug strength;
  - (v) Quantity;
  - (vi) Method of destruction;
  - (vii) Name of the person responsible for the destruction; and
  - (viii) Name of the witness.

8. ~~[7.]~~ A PCH or SPCH that stores and administers controlled substances in an emergency medication kit (EMK) shall comply with the:

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

(k) ~~[(h)]~~ 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.

(l) ~~[(i)]~~

- 1. All medicines kept by the PCH or SPCH shall be kept in a locked place.
- 2. The nurse or CMA ~~administrator or staff person designated by the administrator~~ shall ~~be~~ responsible for administering ~~for supervising the self-administration of~~ medication. ~~[(j)]~~
- 3. The administrator or staff person designated by the administrator shall:
  - a. Be responsible for supervising the self-administration of medication;
  - b. Ensure that all medications requiring refrigeration are kept in a separate locked box in the refrigerator in the medication area; and
  - c. Ensure that drugs for external use are stored separately from those administered by mouth and injection.

(m) ~~[(j)]~~

- 1. A PCH or SPCH that stores and administers non-controlled substances in an EMK shall comply with the:
  - a. Requirement for licensed personnel established by 201 KAR 2:370, Section 2(4)(i); and
  - b. Limitation on the number and quantity of medications established by 201 KAR 2:370, Section 2(4)(b).

2. A PCH or SPCH 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).

(n) ~~[(k)]~~

1. If a resident manifests persistent behavior that might require psychiatric treatment, the PCH or SPCH shall notify the resident's physician or health care practitioner acting within the practitioner's scope of practice to evaluate and direct the resident's care.

2. If the resident's condition does not improve for continued stay in a PCH or SPCH, the physician or health care practitioner shall initiate transfer of the resident to an appropriate facility as soon as possible.

(o) ~~[(l)]~~ Use of restraints.

1. Chemical and physical restraints shall not be used, except as authorized by KRS 216.515(6).

2. Restraints that require a lock and key shall not be used.

3. Emergency use of a manual restraint shall be applied only by appropriately trained personnel if:

a. A resident poses an imminent risk of physical harm to self or others; and

b. The emergency manual restraint is the least restrictive intervention to achieve safety.

4. Restraints shall not be used as:

a. Punishment;

b. Discipline;

c. Convenience for staff; or

d. Retaliation.

(p) ~~[(m)]~~ Each resident shall have an annual medical evaluation by a physician or health care practitioner acting within the practitioner's scope of practice. ~~[-]~~

(q) ~~[(n)]~~ Communicable diseases. If a resident or prospective resident is suspected or confirmed as having a communicable disease for which a reasonable probability of disease transmission exists in the PCH or SPCH, the administrator or staff person designated by the administrator shall:

1. Contact a physician; and

2. Ensure that appropriate measures are taken to treat the resident with the communicable disease and prevent the disease from spreading.

(2) Residential care services. A PCH or SPCH shall provide residential care services to all residents, including:

(a) Room accommodations;

(b) Housekeeping and maintenance services; and

(c) Dietary services.

(3) A PCH or SPCH shall meet the following requirements relating to the provisions of residential care services:

(a) Room accommodations.

1. A PCH or SPCH shall provide each resident with:

a. A bed that is at least thirty-six (36) inches wide;

b. A clean, comfortable mattress with a support mechanism;

c. A mattress cover;

d. Two (2) sheets and a pillow; and

e. Bed covering to keep the resident comfortable.

2. Each bed shall be placed so that a resident does not experience discomfort because of proximity to a radiator, heat outlet, or exposure to a draft.

3. Except for married couples or domestic partners, there shall be separate sleeping quarters for males and females.

4. A PCH or SPCH shall provide:
    - a. Window coverings;
    - b. Bedside tables with reading lamps, if appropriate;
    - c. Comfortable chairs;
    - d. A chest or dresser with a mirror for each resident; and
    - e. A night light.
  5. A resident shall not be housed in a room, detached building, or other enclosure that has not previously been inspected and approved for residential use by the Office of Inspector General and the Department of Housing, Buildings and Construction.
  6. Basement rooms shall not be used for sleeping rooms for residents.
  7. Residents may have personal items and furniture, if feasible.
- (b) Housekeeping and maintenance services.
1. A PCH or SPCH shall:
    - a. Maintain a clean and safe facility free of unpleasant odors; and
    - b. Ensure that odors are eliminated at their source by prompt and thorough cleaning of commodes, urinals, bedpans, and other sources.
  2. A PCH or SPCH shall:
    - a. Have available at all times a quantity of clean linen essential to the proper care and comfort of residents;
    - b. Ensure that soiled clothing and linens receive immediate attention and not be allowed to accumulate;
    - c. Ensure that clothing or bedding used by one (1) resident shall not be used by another resident unless laundered or dry cleaned;
    - d. Ensure that each resident's personal clothing and bed linens are laundered as often as is necessary;
    - e. Maintain responsibility for laundering each resident's personal clothing unless the resident or the resident's family accepts this responsibility;
    - f. Provide laundry equipment for each resident who is capable of, and chooses to launder his or her personal clothing; and
    - g. Label or mark each resident's personal clothing if laundered by the facility for return to the correct resident.
  3. Safety. The condition of the overall environment shall be maintained in such a manner that the safety and well-being of residents, personnel, and visitors is assured.
  4. Maintenance. The premises shall be well kept and in good repair as established in clauses a. through d. of this subparagraph:
    - a. The facility shall insure that the grounds are well kept and the exterior of the building, including the sidewalk, steps, porches, ramps, and fences, are in good repair.
    - b. The interior of the building, including walls, ceilings, floors, windows, window coverings, doors, plumbing, and electrical fixtures, shall be in good repair. Windows and doors shall be screened.
    - c. Garbage and trash shall be stored in areas separate from those used for the preparation and storage of food and shall be removed from the premises regularly. Containers shall be cleaned regularly.
    - d. A pest control program shall be in operation in the facility. Pest control services shall be provided by maintenance personnel of the facility or by contract with a pest control company. Care shall be taken to use the least toxic and least flammable insecticides and rodenticides. The compounds shall be stored under lock if stored by the facility.
- (c) Dietary services.
1. Dining area. A dining area shall be available for the residents.

2. Therapeutic diets. If the facility provides therapeutic diets and the staff member responsible for food services is not a licensed~~license~~ 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. A PCH or SPCH shall meet the nutrition needs of residents in accordance with physician's orders.

c. Except as established in clause e. of this subparagraph, 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:

(i) Substitutions shall provide equal nutritive value;

(ii) The changes shall be recorded on the menu; and

(iii) Menus shall be kept on file for at least 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 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. Between-meal snacks, including an evening snack before bedtime, shall be offered to all residents.

f. Adjustments shall be made if medically contraindicated.

g. Food shall be:

(i) Prepared by methods that conserve nutritive value, flavor, and appearance; and

(ii) Served at the proper temperature and in a form to meet individual needs.

h. A file of tested recipes, adjusted to appropriate yield, shall be maintained.

i. Food shall be cut, chopped, or ground to meet individual needs.

j. If a resident refuses food served, substitutes shall be offered.

k. All opened containers or leftover food items shall be covered and dated when refrigerated.

l. Ice water shall be readily available to the residents at all times.

m. Food services shall be provided in accordance with 902 KAR 45:005.

(4) Personal care services. All PCHs and SPCHs shall provide services to assist residents with activities of daily living to achieve and maintain good personal hygiene, including assistance as needed with:

(a) Bathing. The facility shall provide soap, clean towels, and wash cloths for each resident and ensure that toilet articles such as towels, brushes, and combs are not used in common;

(b) Shaving;

(c) Cleaning and trimming of fingernails and toenails;

(d) Cleaning of the mouth and teeth to maintain good oral hygiene, and care of the lips to prevent dryness and cracking. The facility shall provide all residents with tooth brushes, a dentifrice, and denture containers, if applicable; and

(e) Washing and grooming.

(5) Activity services.

(a) All PCHs and SPCHs shall provide social and recreational activities to:

1. Stimulate physical and mental abilities to the fullest extent;
  2. Encourage and develop a sense of usefulness and self-respect;
  3. Prevent, inhibit, or correct the development of symptoms of physical and mental regression; and
  4. Provide sufficient variety to meet the needs of each resident.
- (b) All PCHs and SPCHs shall meet the requirements established in subparagraphs 1. through 8. of this paragraph relating to the provision of activity services.
1. Staff. The administrator:
    - a. Shall designate a staff member to be responsible for the activity program; and
    - b. May accept services from a volunteer group to assist with carrying out the activity program.
  2. There shall be a planned activity period each day.
  3. The schedule shall be current and posted.
  4. The activity program shall be planned for group and individual activities, both within and outside of the facility.
  5. The staff member responsible for the activity program shall maintain a current list of residents in which precautions are documented regarding if a resident's condition might restrict or modify the resident's participation in the program.
  6. A living or recreation room and outdoor recreational space shall be provided for residents and their guests.
  7. The facility shall provide supplies and equipment for the activity program.
  8. Reading materials, radios, games, and TV sets shall be provided for the residents.
- (c) An SPCH shall collaborate with the agency or team that is working with residents transitioning to community living pursuant to 908 KAR 2:065 to offer basic instruction in ADLs and IADLs to each resident who is identified as working to transition to independent community living pursuant to 908 KAR 2:065. ADL and IADL skills training shall include instruction that is integrated into the normal rhythms of life.
- (6) For purposes of subsection (5)(c) of this section, the following shall apply:
- (a) "Basic instruction" in ADLs and IADLs shall have the same meaning as "assistance with" ADLs and IADLs;
  - (b) An SPCH shall not be responsible for selecting which residents receive basic instruction in ADLs and IADLs; and
  - (c) An SPCH shall not be responsible for ensuring that a resident has mastered each task defined as an ADL or IADL.

Section 6. Mental Illness or Intellectual Disability (MI/ID) Supplement Program Certification.

- (1) Office of Inspector General staff shall visit a personal care home to certify eligibility to participate in the MI/ID Supplement Program established by 921 KAR 2:015, Section 13.
- (2) A personal care home's initial MI/ID Supplement Program certification inspection:
  - (a) May be separate from an unannounced inspection conducted in accordance with KRS 216.530; and
  - (b) Shall be in effect until the next licensure survey conducted in accordance with KRS 216.597(7)(c)2.
- (3) During an MI/ID Supplement Program inspection, Office of Inspector General staff shall:
  - (a) Observe and interview residents and staff; and
  - (b) Review records to assure the facility meets the following criteria:
    1. Facility maintains documentation of staff completion of the training required by 921 KAR 2:015, Section 14(1) through (4);
    2. Facility ensures that:

- a. The staff person who attended the one (1) day MI/ID training workshop shares information obtained from the workshop with all other direct care staff through annual in-service training or orientation pursuant to Section 4(10)(h)3.f. of this administrative regulation; and
  - b. If medication is administered to residents, administration shall be done by a nurse, CMA, or KMA in which case the nurse, CMA, or KMA shall demonstrate a knowledge of psychotropic drug side effects.
- (4) Office of Inspector General staff shall review the facility's documentation of MI/ID training prior to performing a record review during the MI/ID Supplement Program inspection process.
- (5) If at least thirty-five (35) percent of the resident population meets the criteria established by 921 KAR 2:015, Section 13(1)(c)2. on the day of the visit, a personal care home shall be deemed to have an ongoing qualifying percentage in the MI/ID Supplement Program effective with the month of request for certification in the program.
- (6) Office of Inspector General staff shall provide the Department for Community Based Services with a completed STS-4, Mental Illness or Intellectual Disability (MI/ID) Supplement Certification Survey, incorporated by reference in 921 KAR 2:015, Section 17(1)(d), within fifteen (15) working days of an:
  - (a) Initial survey; or
  - (b) Inspection conducted in accordance with KRS 216.530 and 216.597(7)(c)2.
- (7) The Office of Inspector General shall provide the Department for Community Based Services with a copy of a Type A citation issued to a specialized personal care home that participates in the MI/ID Supplement Program by the fifth working day of month following the month the citation was issued.

#### Section 7. 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 a PCH or SPCH license in accordance with KRS 216.597(7)(a) if:
  - (a) There has been a substantial failure by the facility to comply with the provisions of:
    - 1. KRS 216.510 through 216.597, or 216.789; or
    - 2. This administrative regulation;
  - (b) The facility allows, aids, or abets the commission of any illegal act in the provision of 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 a Long Term Care Facility; 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 established 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 902 KAR 20:008, Section 2(4)

(b).

(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 8. [~~Section 5.~~] Material Incorporated by Reference.

(1) The form, "SMI Screening Form", August 2019, is incorporated by reference.

(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., or it may be viewed on the Office of Inspector General's website at <https://chfs.ky.gov/agencies/os/oig/dhc/pages/lrc.aspx>.

*ADAM MATHER, Inspector General*  
*ERIC C. FRIEDLANDER, Secretary*

APPROVED BY AGENCY: November 21, 2023

FILED WITH LRC: December 6, 2023 at 1:20 p.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on February 26, 2024, at 9:00 a.m. using the CHFS Office of Legislative and Regulatory Affairs Zoom meeting room. The Zoom invitation will be emailed to each requestor the week prior to the scheduled hearing. Individuals interested in attending this virtual hearing shall notify this agency in writing by February 19, 2024, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends virtually will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until February 29, 2024. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Krista Quarles, Policy Analyst, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; Phone: 502-564-7476; Fax: 502-564-7091; 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 administrative regulation establishes minimum licensure requirements for the operation of and services provided by personal care homes (PCHs), including specialized personal care homes (SPCHs).

**(b) The necessity of this administrative regulation:**

This administrative regulation is necessary to comply with KRS 216B.042, which requires the Cabinet for Health and Family Services to promulgate administrative regulations necessary for the proper administration of the licensure function, including licensure standards and procedures to ensure safe, adequate, and efficient health services. This administrative regulation is also necessary to comply with KRS 216.597(7)(a), which requires the cabinet to promulgate administrative regulations to establish an initial and relicensure review process for personal care homes or specialized personal care homes, including procedures related to applying for, reviewing, and approving, denying, or revoking licensure, as well as the conduct of hearings upon appeal as governed by KRS Chapter 216B.

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

This administrative regulation conforms to the content of KRS 216B.042 by establishing standards for licensed personal care homes. This administrative regulation also conforms to the content of KRS 216.597 by establishing licensure procedures and a process for appeals.

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

This administrative regulation assists in the effective administration of the statutes by establishing standards for licensed personal care homes.

**(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:**

This amendment: 1. Adds KRS 216.597 to the STATUTORY AUTHORITY section and the NECESSITY, FUNCTION, AND CONFORMITY paragraph; 2. Adds a definition of "nurse" and "temporary condition" to Section 1; 3. Adds a new Section 2, Licensure Application and On-site Visits, as required by KRS 216.597(7); 4. Permits a nonambulatory resident with a temporary condition to be admitted or continue residing in a PCH or SPCH in accordance with KRS 216.597(3); 5. Requires each SPCH to provide access to confidential and secure telehealth services unless access is impossible due to a lack of broadband services or appropriate physical space for residents; 6. Permits PCH or SPCH residents to arrange for additional services under direct contract or arrangement with an outside party pursuant to KRS 216.597(5), if permitted by the policies of the facility; 7. Requires each PCH or SPCH to have a written policy in accordance with KRS 216.597(6)(c) that describes 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 to walk, transfer, or move from place to place; 8. If nursing tasks are delegated in a PCH or SPCH, requires the facility to have a written policy regarding the

supervision of unlicensed personnel performing the delegated tasks, including how the facility ensure compliance with the supervision requirements of 201 KAR 20:400, Section 4; 9. Requires compliance with the staffing requirements of KRS 216.597(6); 10. Requires a nurse to be available in person, by telephone, or by other means of live, two-way communication during the times that unlicensed staff perform delegated nursing tasks; 11. Requires unlicensed staff who administer medications under the delegation of a nurse to have a certified medication aide (CMA) or Kentucky medication aide (KMA) credential; 12. Expands the requirement that currently authorizes only a nurse to administer controlled substances by allowing CMAs to administer controlled substances if delegated by a nurse; 13. Transfers OIG requirements related to the certification of SPCHs for participation in the Mental Illness or Intellectual Disability (MI/ID) Program from 921 KAR 2:015, Section 15 to this administrative regulation as a new Section 6; and 14. Adds a new Section 7, Denial and Revocation, as required by KRS 216.597(7) (a).

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

This amendment is necessary to align with the 2023 passage of SB 110, which amended KRS 194A.705(2)(c) to require all long-term care facilities that provide basic health and health-related services or dementia care services to ensure that unlicensed staff who administer oral or topical medications, or preloaded injectable insulin to residents under the delegation of a nurse to have successfully completed a medication aide training and skills competency evaluation program approved by the Kentucky Board of Nursing (KBN). Additionally, the cabinet entered into a Third Amended Settlement Agreement (TASA) on June 21, 2023, with Kentucky Protection and Advocacy as it relates to services provided to individuals with serious mental illness (SMI). One of the provisions of the TASA requires that the cabinet promulgate administrative regulations within 180 days regarding personal care homes. Specifically, the regulation must require: "... access to confidential and secure telehealth services (unless that access is impossible to provide due to lack of broadband service or lack of an appropriate physical space) for residents of all PCHs that participate in the Mental Illness or Intellectual Disability Supplement Program pursuant to 921 KAR 2:015 Section 13 and all PCHs that have more than thirty-five percent (35%) residents with SMI as shown in the Annual Long Term Care Utilization and Service Report data." This amendment therefore adds language that aligns with the TASA requirement for access to telehealth services.

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

This amendment conforms to the content of KRS 216B.042 by establishing standards for licensed personal care homes. This amendment also conforms to the content of SB 110 from the 2023 legislative session, codified at KRS 194A.705(2) (c), because the statute applies to all long-term care facilities that provide basic health and health-related services, including personal care homes. As a category of personal care home licensed under this administrative regulation, specialized personal care homes are also subject to the requirements of KRS 194A.705(2)(c).

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

This amendment will assist in the effective administration of the statutes by establishing standards that align with the statutory requirements for licensed personal care homes.

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

This administrative regulation impacts licensed personal care homes. Currently, there are 97 freestanding personal care homes and 64 long-term care facilities with personal care home beds.

**(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:**

PCHs and SPCHs must ensure that unlicensed staff who administer oral or topical medications to residents under the delegation of a nurse be a certified medication aide I or Kentucky medication aide, or be a certified medication aide II to administer preloaded injectable insulin to residents. In addition, SPCHs must ensure resident access to telehealth services, if feasible.

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

If a PCH or SPCH provides nursing services such as medication administration and does not currently have a nurse on staff or use unlicensed personnel with a CMA or KMA credential as required by KRS 194A.705(2)(c), the facility will incur increased staffing costs.

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

The use of properly trained and competent certified 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 of PCHs and SPCHs.

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

**(a) Initially:**

There are no additional costs to the Office of Inspector General for implementation of this amendment.

**(b) On a continuing basis:**

There are no additional costs to the Office of Inspector General for implementation of this amendment on a continuing basis.

**(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 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:**

No increase in fees or funding is necessary to implement this amendment.

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

This amendment does not establish or increase any fees.

**(9) TIERING: Is tiering applied?**

(Explain why or why not) Tiering is not applicable as compliance with this administrative regulation applies equally to all PCHs and SPCHs regulated by it.

## 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 the Cabinet for Health and Family Services, Office of Inspector General, and licensed personal care homes, including specialized personal care homes.

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

KRS 216.597, 216B.042

**(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?**

This amendment will not generate any additional revenue.

**(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?**

This amendment will not generate any additional revenue during subsequent years.

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

This amendment imposes no additional costs on the administrative body.

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

This amendment imposes no additional costs on the administrative body during subsequent years.

**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?**

If a PCH or SPCH provides nursing services, such as medication administration, and does not currently have a nurse on staff or use unlicensed personnel with a CMA or KMA credential as required by KRS 194A.705(2)(c), the facility will incur increased staffing costs.

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

If a PCH or SPCH provides nursing services, such as medication administration, and does not currently have a nurse on staff or use unlicensed personnel with a CMA or KMA credential as required by KRS 194A.705(2)(c), the facility will incur increased staffing costs.

**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)] There will be no major fiscal economic impact as a result of this regulation.

## FEDERAL MANDATE ANALYSIS COMPARISON

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

21 C.F.R. Part 1317

**(2) State compliance standards.**

KRS 194A.705(2)(c), 216.597, 216B.042

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

21 C.F.R. Part 1317 sets forth the Drug Enforcement Administration's rules for the safe disposal and destruction of damaged, expired, returned, recalled, unused, or otherwise unwanted controlled substances.

**(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 more strict than federal laws or regulations.

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

Not applicable.