

STATUTORY AUTHORITY: 216B.042

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.042 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. This administrative regulation provides minimum licensure requirements for the operation of specialty intermediate care clinics.

Section 1. Definitions. (1) "Clinic" or "specialty intermediate care (IC) clinic" means a clinic located on the grounds of a state-owned facility licensed pursuant to 902 KAR 20:086 as an intermediate-care facility for the intellectually and developmentally disabled.

(2) "Developmental disability" is defined by 42 U.S.C. 15002(8)(A) as a severe, chronic disability of an individual that:

(a) Is attributable to a mental or physical impairment or combination of mental and physical impairments;
(b) Is manifested before the individual attains age twenty-two (22);
(c) Is likely to continue indefinitely;
(d) Results in substantial functional limitations in three (3) or more areas of major life activity, including:
   1. Self-care;
   2. Receptive and expressive language;
   3. Learning;
   4. Mobility;
   5. Self direction;
   6. Capacity for independent living; or
   7. Economic self-sufficiency; and
   (e) Reflects the individual’s need for a combination and sequence of special, interdisciplinary, or generic services, individualized supports, or other forms of assistance that are of lifelong or extended duration and are individually planned and coordinated.

(3) "Intellectual disability" means an individual has:
(a) Significantly sub-average intellectual functioning;
(b) An intelligence quotient of seventy (70) or below;
(c) Concurrent deficits or impairments in present adaptive functioning in at least two (2) of the following areas:
   1. Communication;
   2. Self-care;
   3. Home living;
   4. Social or interpersonal skills;
   5. Use of community resources;
   6. Self-direction;
   7. Functional academic skills;
   8. Work;
   9. Leisure; or
   10. Health and safety; and
(d) Had an onset prior to eighteen (18) years of age.

(4) "Patient" means an individual who receives services provided by a specialty IC clinic and who:

(a) Is not a resident of, but qualifies for admission to an intermediate-care facility for the intellectually and developmentally disabled by meeting the patient status criteria established in 907 KAR 1:022, Section 4; or

(b) Is a resident of an intermediate-care facility for the intellectually and developmentally disabled which contracts with, or makes arrangements with the specialty IC clinic for outpatient services.

Section 2. Licensure Application and Fee. (1) An applicant for licensure as a specialty IC clinic shall complete and submit to the Office of the Inspector General an Application for License to Operate a Health Facility or Service, pursuant to 902 KAR 20:008, Section 2(2)(f).

(2) The initial and annual fee for licensure as a specialty clinic shall be $500.

Section 3. Scope of Operations and Services. (1) Services provided by a specialty IC clinic shall be individualized to meet the treatment needs of each of the specialty IC clinic’s patients. Patients may receive one (1) or more of the following services from the clinic:

(a) Dental services;
(b) Psychiatric services;
(c) Psychological services;
(d) Psychotropic medication management;
(e) Neurology;
(f) Epileptology;
(g) Preventive health care;
(h) Medical assessment and treatment;
(i) Occupational therapy;
(j) Physical therapy;
(k) Speech therapy;
(l) Nutritional or dietary consultation;
(m) Mobility evaluation or treatment;
(n) Behavioral support services;
(o) Audiology;
(p) Ophthalmology;
(q) Pharmacy;
(r) Medication consultation;
(s) Medication management;
(t) Seizure management;
(u) Behavioral support services;
(v) Diagnostic services;
(w) Clinical laboratory services;
(x) Physician services; or
(y) Laboratory services.

(2) Off-site services.

(a) Specialty IC clinic personnel as identified in Section 5(4) of this administrative regulation may provide services off-site at a local health department or in a health facility licensed under 902 KAR Chapter 20 if the specialty IC clinic has an agreement to provide the off-site services at the health department or licensed health facility’s location for the purpose of improving patient accessibility or accommodating the patient’s individualized healthcare needs.
(b) A psychologist, psychiatrist, behavior specialist, or board certified behavior analyst directly employed by, or under contract with a specialty IC clinic, may provide behavioral assessments or consultation off-site:
   1. In a patient’s home; or
   2. At a day service or other service site where the patient receives services.

Section 4. Administration and Policies. (1) The licensee shall have legal responsibility for the specialty IC clinic, including responsibility for ensuring compliance with federal, state, and local laws and regulations pertaining to the operation of the clinic.
   (2) The licensee shall establish lines of authority and designate an administrator who shall be principally responsible for the daily operation of the specialty IC clinic.
   (3) A specialty IC clinic shall establish and follow written administrative policies covering all aspects of operation, including:
      (a) A description of organizational structure, staffing, and allocation of responsibility and accountability;
      (b) Policies and procedures for the guidance and control of personnel performances;
      (c) A written program narrative describing in detail the:
         1. Services offered;
         2. Methods and protocols for service delivery;
         3. Qualifications of personnel involved in the delivery of the services; and
         4. Goals of the service;
      (d) A description of how administrative and patient care records and reports are maintained; and
      (e) Procedures to be followed if the clinic performs any functions related to the storage, handling, and administration of drugs and biologicals.
   (4) Patient Care Policies. A specialty IC clinic shall develop patient care policies which address:
      (a) A description of the services the clinic provides directly and those provided through agreement;
      (b) Guidelines for the medical management of health problems which include the conditions requiring medical consultation or patient referral; and
      (c) Procedures for the annual review and evaluation of the services provided by the clinic.

Section 5. Personnel. (1)(a) A specialty IC clinic shall have a medical director who is a licensed physician.
   (b) The specialty IC clinic's medical director shall:
      1. Be responsible for all medical aspects of the clinic and provide direct medical services in accordance with the Medical Practice Act, KRS Chapter 311;
      2. Provide medical direction, supervision, and consultation to the staff;
      3. In conjunction with the registered nurse described in subsection (2) of this section, participate in the development, execution, and periodic review of the clinic's written policies and services;
      4. Periodically review the clinic's patient records, provide medical orders, and provide medical care services to patients of the clinic;
      5. Be present for weekly consultation, or delegate responsibility for weekly consultation to another physician employed by, or under contract with the specialty IC clinic if a temporary absence is necessary; and
      6. Be available within one (1) hour through direct telecommunication for consultation, assistance with medical emergencies, or patient referral. If a temporary absence is necessary, the
medical director shall designate another physician who is employed by, or under contract with the specialty IC clinic to be available within one (1) hour through direct telecommunication for consultation, assistance with medical emergencies, or patient referral.

(2) A specialty IC clinic shall have at least one (1) registered nurse who shall:
(a) Have at least one (1) year experience in treating or working with individuals with an intellectual disability and a developmental disability;
(b) Participate in the development, execution, and periodic review of the written policies governing the services the clinic provides;
(c) Participate with the medical director in periodic review of patient health records;
(d) Provide services in accordance with clinic policies, established protocols, the Nurse Practice Act (KRS Chapter 314), and with administrative regulations promulgated thereunder;
(e) Arrange for or refer patients to needed services that cannot be provided at the clinic; and
(f) Assure that adequate patient health records are maintained and transferred when patients are referred.

(3) A specialty IC clinic shall maintain, through direct employment or contract, a sufficient number of qualified personnel to provide effective patient care and all other related services.

(4) Qualified personnel directly employed by, or under contract with a specialty IC clinic shall include:
(a) Physicians;
(b) Dentists;
(c) Dental hygienists;
(d) Physician assistants;
(e) Nurse practitioners;
(f) Registered nurses;
(g) Psychologists;
(h) Psychiatrists;
(i) Pharmacists;
(j) Audiologists;
(k) Optometrists;
(l) Dieticians;
(m) Behavior specialists;
(n) Board certified behavior analysts;
(o) Ophthalmologists;
(p) Physical therapists;
(q) Speech therapists;
(r) Occupational therapists;
(s) Physical therapist assistants; and
(t) Occupational therapist assistants.

(5)(a) Prior to providing any service described in Section 3(1) of this administrative regulation, all qualified personnel as identified in subsection (4) of this section shall submit to an in-state criminal background information check conducted by the Justice and Public Safety Cabinet or Administrative Office of the Courts.

(b) An out-of-state criminal background information check shall be obtained for any qualified personnel who have resided or been employed outside Kentucky.

(c) A clinic shall not knowingly employ any person who has been convicted of a felony offense under:
1. KRS Chapter 209;
2. KRS Chapter 218A;
3. KRS 507.020, 507.030, and 507.040;
4. KRS Chapter 509;
5. KRS Chapter 510;
6. KRS Chapter 511;
7. KRS Chapter 513;
8. KRS 514.030;
9. KRS Chapter 530;
10. KRS Chapter 531;
11. KRS 508.010, 508.020, 508.030, and 508.032;
12. A criminal statute of the United States or another state similar to subparagraphs 1 to 11 of this paragraph; or
13. A violation of the uniform code of military justice or military regulation similar to subparagraphs 1 to 11 of this paragraph which has caused the person to be discharged from the Armed Forces of the United States.

(d) A person who has received a pardon for an offense specified in paragraph (c) or has had the record of the offense expunged may be employed.

(6) A specialty IC clinic shall maintain written personnel policies which shall be available to all employees.

(7) A specialty IC clinic shall maintain a written job description for each position which shall be reviewed and revised as necessary.

(8) A specialty IC clinic shall maintain current personnel records for each employee. An employee’s personnel record shall include the following:

(a) Employee’s name and address;
(b) Evidence that the health care professional has a valid license or other valid credential required for the professional to be able to practice;
(c) Record of training and experience; and
(d) Record of performance evaluations.

(9)(a) Specialty IC clinic personnel shall attend in-service training programs relating to their respective job duties. These training programs shall include:

1. Thorough job orientation for new personnel;
2. Regular in-service training programs;
3. Behavior management procedures and techniques;
4. Training in the detection and reporting of suspected abuse or neglect of a child or adult;
5. Training in the field of intellectual and developmental disabilities; and

(b) A written document describing the training programs completed by all clinic employees shall be maintained on the premises of the clinic.

Section 6. Medical Records. (1) A specialty IC clinic shall maintain medical records which contain the following:

(a) Name of the patient;
(b) Description of each medical visit or contact, including:
1. Date of the visit;
2. Condition or reason for the visit;
3. Name of health care practitioner providing the service;
4. Description of the services provided; and
5. Any medications or treatments prescribed;
(c) Medical or social history relevant to the services provided, including data obtained from other providers;
(d) Names of referring physicians, if any, and physicians orders for special diagnostic ser-
vice; and
(e) Documentation of all referrals made, including the reason for the referral and to whom the patient was referred.

(2) A specialty IC clinic shall maintain confidentiality of patient records at all times pursuant to and in accordance with federal, state and local laws and administrative regulations, including the privacy standard promulgated pursuant to Health Insurance Portability and Accountability Act (HIPAA), 45 C.F.R. 160 and 164.

(3) A specialty IC clinic shall:
(a) Establish systematic procedures to assist in continuity of care if the patient moves to another source of care;
(b) Transfer medical records or an abstract upon request, subject to required releases and authorizations; and
(c) Have a specific location designated for the storage and maintenance of the clinic's medical records, maintain scanned copies of the original medical records in an electronic format, or maintain electronic health records, available for copying to a disk or printing at the clinic.

(4)(a) Medical records shall be maintained by the clinic for a period of six (6) years following the last treatment, assessment, or visit made by the patient, or three (3) years after the patient reaches age eighteen (18), whichever is longer.
(b) A provision shall be made for written designation of a specific location for the storage of medical records if the specialty IC clinic ceases to operate because of disaster, or for any other reason.
(5) A specialty IC clinic shall safeguard each clinic's medical records and content against loss, defacement, and tampering.

Section 7. Provision of Services. (1) Equipment. Equipment used for direct patient care shall comply with the following:
(a) The licensee shall establish and follow a written preventive maintenance program to ensure that equipment shall be operative, properly calibrated, and cleaned regularly;
(b) All personnel engaged in the operation of diagnostic equipment shall have adequate training and be currently licensed, registered or certified in accordance with applicable state statutes and administrative regulations; and
(c) A written plan shall be developed and maintained to provide for training of personnel in the safe and proper usage of the equipment.

(2) Diagnostic services. Diagnostic services shall be performed in accordance with the specialty IC clinic's protocol.
(a) Protocols for diagnostic examinations shall be developed by the medical director.
(b) Diagnostic services shall be provided under the supervision of a physician who is qualified by advanced training and experience in the use of the specific technique utilized for diagnostic purposes.
(c) Physical examination services shall be nonabusive and provided in a manner which ensures the greatest amount of safety and security for the patient.
1. Personnel performing physical examinations shall have adequate training and be currently licensed, registered, or certified in accordance with applicable Kentucky statutes and administrative regulations.
2. Personnel performing physical examinations shall be limited by the relevant scope of practice of state licensure.
(3) Referrals. A specialty IC clinic shall refer a patient for services that cannot be provided at the clinic.
(4) Restraints
(a) A specialty IC clinic shall promote a restraint free environment and ensure that restraints are used only for medical emergencies or if the resident poses an immediate risk to self or others.

(b) Use of any type of restraint as a health-related protection shall be prescribed by a physician if necessary during the conduct of specific medical procedure.

(c) The specialty IC clinic shall have a system to monitor and decrease the use of physical restraint and pre-sedation.

Section 8. Physical Environment. (1) Accessibility. A specialty IC clinic shall meet requirements for making buildings and facilities accessible to and usable by individuals with physical disabilities pursuant to KRS 198B.260 and administrative regulations promulgated thereunder.

(2) Fire safety. A specialty IC clinic shall be approved by the State Fire Marshal's office prior to initial licensure.

(3) Housekeeping and maintenance services.

(a) Housekeeping. A specialty IC clinic shall maintain a clean and safe facility free of unpleasant odors. Odors shall be eliminated at their source by prompt and thorough cleaning of commodes, urinals, bedpans and other sources.

(b) Maintenance. The premises shall be well kept and in good repair as follows:

1. The clinic shall insure that the grounds are well kept and the exterior of the building, including the sidewalks, steps, porches, ramps, and fences are in good repair;

2. 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 which can be opened for ventilation shall be screened;

3. 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;

4. A pest control program shall be in operation in the clinic. Pest control services shall be provided by maintenance personnel of the facility or by contract with a pest control company. The compounds shall be stored under lock;

5. Sharp wastes, such as broken glass, scalpel blades, and hypodermic needles shall be segregated from other wastes and aggregated in rigid disposable containers immediately after use. Needles and syringes shall not be cut, dismantled, or destroyed after use but shall be placed intact directly into a rigid container. The rigid containers of sharp wastes shall either be incinerated, on site or off site, or disposed of in a sanitary landfill approved pursuant to 401 KAR 47:080; and

6. The clinic shall establish a written policy for the handling and disposal of all infectious, pathological, and contaminated waste if the clinic generates them. Any incinerator used for the disposal of waste shall be in compliance with 401 KAR 59:020 or 61:010.

a. (i) Infectious waste shall be placed in double impervious plastic bags and each bag shall be two (2) mils in thickness.

(ii) A bag, if full, shall not exceed twenty five (25) pounds.

(iii) All bags shall be securely closed and a tag, which reads "INFECTIONOUS WASTE" and identifies the clinic from which the waste is being removed and shall be attached to the bag in a conspicuous manner.

b. All unpreserved tissue specimens procedures shall be incinerated on or off site.

c. The following wastes shall be sterilized before disposal or be disposed of by incineration if they are combustible:

(i) Dressings and materials from open or contaminated wounds;

(ii) Waste materials and disposable linens from isolation rooms;
(iii) Culture plates;
(iv) Test tubes;
(v) Sputum cups; and
(vi) Contaminated sponges and swabs. (37 Ky.R. 1142; 1731; 2019; eff. 3-4-2011; TAM eff. 12-10-2012; Crt eff. 1-11-2019.)