

**Technical Amendment
March 20, 2020**

902 KAR 20:450. Ambulatory infusion agencies.

RELATES TO: KRS 17.500(8), 216B.042, 439.3401, 42 C.F.R. 486.500–486.525, 42 C.F.R. 488.1000–488.1050, 45 C.F.R. Parts 160, 164, 42 U.S.C. 1320d-2–1320d-8

STATUTORY AUTHORITY: KRS 216B.042

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. This administrative regulation establishes minimum licensure requirements for the operation of ambulatory infusion agencies that provide infusion therapy services in a patient's home or in an ambulatory infusion center.

Section 1. Definitions. (1) "Ambulatory infusion center" means an outpatient treatment center that provides infusion therapy services, excluding an off-campus, Kentucky-hospital owned center or service that meets the licensing exemption criteria of 900 KAR 6:130, Section 3(3).

(2) "Home" means a place of residence used as the home of an individual, including an institution that is used as a home. An institution used as a home shall not include a:

- (a) Hospital, including critical access hospital; or
- (b) Long-term care facility defined by KRS 216.510(1).

(3) "Infusion drug" means a parenteral drug or biological administered intravenously, or subcutaneously for an administration period of fifteen (15) minutes or more, in the patient's home or in an ambulatory infusion center through:

- (a) An injection; or
- (b) A pump that is an item of durable medical equipment, excluding:
 - 1. An insulin pump system; or
 - 2. A self-administered drug or biological on a self-administered drug exclusion list.

(4) "Infusion therapy services" means the preparation, administration, or furnishing of parenteral medications, parenteral nutritional services, or administration of drugs intrathecally to an individual in:

- (a) The individual's home; or
- (b) An ambulatory infusion center.

Section 2. Licensure Application and Fees. (1) An applicant for an initial, provisional license or annual renewal as an ambulatory infusion agency shall submit to the Office of Inspector General:

- (a) A completed Application for License to Operate an Ambulatory Infusion Agency; and
- (b) An accompanying fee in the amount of \$500, made payable to the Kentucky State Treasurer.

(2)(a) Name change. An ambulatory infusion agency shall:

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

(b) Change of location. An ambulatory infusion agency shall not change the location where a facility is operated until an Application for License to Operate an Ambulatory Infusion Agency accompanied by a fee of \$100 is filed with the Office of Inspector General.

(c) Change of ownership.

1. The new owner of an agency shall submit to the Office of Inspector General an Application for License to Operate an Ambulatory Infusion Agency 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 ambulatory infusion agency or capital stock or voting rights of a corporation is purchased, leased, or otherwise acquired by one (1) person from another.

(3) An extension site location shall not be allowed for any entity licensed under this administrative regulation.

(4) An ambulatory infusion agency shall have an office location in Kentucky.

Section 3. Scope of Operation and Services. (1) A licensee:

(a) Shall furnish infusion therapy services to an individual with an acute or chronic condition that requires administration of infusion drugs in the home or an ambulatory infusion center;

(b) Shall ensure the safe and effective provision and administration of infusion therapy services on a seven (7) day-a-week, twenty-four (24) hour-a-day basis, if provided in the patient's home;

(c) Shall be accredited by a national accrediting organization that meets the requirements of 42 C.F.R. 488.1000 to 488.1050 within one (1) year of initial, provisional licensure;

(d) Shall ensure that each patient's plan of care is established by a physician, or other prescribing practitioner as authorized under the practitioner's scope of practice, who shall be responsible for:

1. Prescribing the type, amount, and duration of the infusion therapy services that are to be furnished; and

2. Review of each patient's plan of care:

a. At least every thirty (30) days; or

b. As often as deemed necessary in accordance with the physician or prescribing practitioner's order on file in the patient's medical record;

(e) Shall provide the skilled nursing services component of infusion therapy services in accordance with the patient's plan of care, including:

1. Clinical notes that shall be signed, recorded, and incorporated in the patient's medical record within three (3) working days of providing the service;

2. Notifying the pharmacist, prescribing practitioner, and applicable agency staff regarding any significant change in the patient's condition; and

3. Patient education and monitoring; and

(f) May provide other professional services in addition to the skilled nursing services component, such as pharmacy services or durable medical equipment required for the delivery of infusion therapy services.

(2)(a) If an ambulatory infusion agency has not obtained accreditation in accordance with subsection (1)(c) of this section within one (1) year of initial licensure, the agency may request an extension to complete the accreditation process.

(b) A request for extension shall:

1. Be submitted in writing to the Office of Inspector General at least sixty (60) days prior to the date of annual renewal;

2. Include evidence that the agency has initiated the process of becoming accredited within sixty (60) days of initial, provisional licensure and is continuing its efforts to obtain accreditation; and

3. Include an estimated timeframe by which approval of accreditation is anticipated, not to exceed two (2) years from the date of initial, provisional licensure.

(3) A licensee's provisional licensure status shall end on the date that the agency obtains accreditation.

(4) Proof of accreditation shall be provided to the Office of Inspector General:

- (a) Upon receiving accreditation; and
- (b) At the time of annual renewal.

(5) If an ambulatory infusion agency loses its accreditation or becomes accredited by a different accrediting organization, the licensee shall notify the Office of Inspector General no later than thirty (30) days from the date that:

- (a) The licensee's accreditation was terminated; or
- (b) Accreditation by a different organization that meets the requirements of 42 C.F.R. 488.1000 to 488.1050 took effect.

(6) The cabinet shall revoke a license if an ambulatory infusion agency fails to meet one (1) of the following requirements:

- (a) Become accredited in accordance with subsection (1)(c) of this section;
- (b) Request an extension in accordance with subsection (2) of this section;
- (c) Achieve accreditation within two (2) years from the date of initial, provisional licensure if a request for extension is submitted; or
- (d) Maintain accreditation.

Section 4. Inspections. (1) If an ambulatory infusion agency demonstrates evidence of full accreditation, the annual renewal process shall not require an on-site survey by the cabinet.

(2) 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 fully accredited ambulatory infusion agency if the cabinet deems necessary.

Section 5. Administration and Operation. (1) Licensee. The licensee shall be legally responsible for:

- (a) The operation of the ambulatory infusion agency;
- (b) Ensuring compliance with federal, state, and local laws and administrative regulations pertaining to the operation of the agency;
- (c) Designating an administrator who shall be responsible for the daily operation of the agency;
- (d) Establishing and implementing written administrative policies covering all aspects of operation, including:

1. A description of the agency's organizational structure, staffing, and allocation of responsibility and accountability;

2. Procedures for the evaluation of personnel performance; and

3. A narrative describing in detail:

- a. The services offered by the agency; and
- b. Qualifications of personnel involved in the delivery of services, including verification that each nurse employed directly or by contract has a license in good standing from the Kentucky Board of Nursing;

(e) Establishing procedures for the handling and administration of drugs and biologicals;

(f) Developing written infection control policies that are consistent with Centers for Disease Control guidelines, available at <https://www.cdc.gov/infectioncontrol/pdf/guidelines/environmental-guidelines-P.pdf>, including:

1. Prevention of disease transmission; and

2. Cleaning, disinfection, and sterilization methods used for equipment and the environment;

and

(g) Establishing guidelines to ensure the coordination of treatment with other health facilities and practitioners that deliver services to patients of the agency.

(2) Background checks. All owners and agency personnel in a position that involves providing direct services shall:

(a) Have a criminal record check performed upon initial hire through the Administrative Office of the Courts or the Kentucky State Police;

(b) Not have a criminal conviction, or plea of guilty, to a:

1. Sex crime as specified in KRS 17.500(8);

2. Violent crime as specified in KRS 439.3401;

3. Felony offense related to:

a. Theft;

b. Abuse, possession, or sale of illegal drugs; or

c. Abuse, neglect, or exploitation of a child or an adult; or

4. Misdemeanor offense related to abuse, neglect, or exploitation of a child or an adult; and

(c) Not be listed on the following:

1.~~[a.]~~ Central registry established by 922 KAR 1:470;

2.~~[b.]~~ Nurse aide or home health aide abuse registry established by 906 KAR 1:100; or

3.~~[c.]~~ Caregiver misconduct registry established by 922 KAR 5:120.

(3) Personnel record. A personnel record shall be kept on each staff member and shall contain the following items:

(a) Name and address;

(b) Verification of all training and experience, including documentation of the employee's professional licensure status, if applicable;

(c) Verification of submission to the background check requirements of subsection (2) of this section;

(d) Annual performance appraisals; and

(e) Employee incident reports.

Section 6. Patient records. (1) Ownership.

(a) Medical records shall be the property of the ambulatory infusion agency.

(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.

(2) Confidentiality and Security: Use and Disclosure.

(a) The agency shall maintain the confidentiality and security of patient 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 agency may use and disclose patient 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 ambulatory infusion agency 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.

(d) Retention of records. After a patient's death or discharge, the completed medical record shall be placed in an inactive file and retained for at least:

1. Six (6) years; or

2. Three (3) years after the patient reaches the age of majority in accordance with KRS 2.015, whichever is longer.

(3) The agency shall:

(a) Designate a specific location for the maintenance and storage of the agency's medical records;

(b) Have provisions for storage of medical records in the event the agency ceases to operate; and

(c) Safeguard the record and its content against loss, defacement, or tampering.

Section 7. Incorporation by Reference. (1) The form, OIG 008, "Application for License to Operate an Ambulatory Infusion Agency", September 2019 edition, 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. (46 Ky.R. 2281; eff. 2-27-2020; TAm eff. 3-202-2020.)