

KENTUCKY BOARD OF EMERGENCY MEDICAL SERVICES
(New Administrative Regulation)

202 KAR 7:596. Mobile integrated healthcare licensure.

RELATES TO: KRS 311A.010, 311A.020, 311A.025, 311A.030, 311A.170, 311A.190, 29 C.F.R. § 1910.1030

STATUTORY AUTHORITY: KRS 311A.020, 311A.025, 311A.030, 311A.190

NECESSITY, FUNCTION, AND CONFORMITY: KRS 311A.030 requires the Kentucky Board of Emergency Medical Services to promulgate administrative regulations establishing requirements for licensing, inspecting, and regulating mobile integrated healthcare programs. This administrative regulation establishes the requirements for mobile integrated healthcare program licensure.

Section 1. Definitions.

- (1) "Discharge planner" means a person coordinating the transition of the patient from the care facility to another location and who ensures that the services and care that the patient will need are coordinated.
- (2) "Home health agency" means an appropriately licensed organization that provides skilled nursing care and therapy services in eligible patients' homes in accordance with applicable federal, state and local requirements.
- (3) "Mobile integrated healthcare" or "MIH" is defined by KRS 311A.010(18).
- (4) "Organization" means any business entity created under the laws of the Commonwealth of Kentucky.
- (5) "Patient care planning" means written documents that help empower patients with complex conditions to better manage their own care. These plans are meant to be written collaboratively with the patient and family and incorporate the patient's and family's goals, preferences for care, and action plans for exacerbations of conditions.
- (6) "Primary care provider" means a physician (Doctor of Medicine or Doctor of Osteopathy), nurse practitioner, or physician assistant licensed or certified under Kentucky law, who provides, coordinates, or helps a patient access a range of healthcare services.

Section 2. Applying for a Mobile Integrated Healthcare Program License. An individual or organization applying for an MIH program license shall submit to the KBEMS office:

- (1) A completed Mobile Integrated Healthcare Program License Application;
- (2) The application fee as established in 202 KAR 7:030;
- (3) A current map or the ZIP codes of the MIH program's intended service area;
- (4) A written description of the:
 - (a) Program;
 - (b) Service area; and
 - (c) Specific services to be provided.

Section 3. Mobile Integrated Healthcare Program Licensure.

- (1) The KBEMS office shall issue a Class V mobile integrated healthcare program license to an individual or organization that satisfies the requirements of this section and section 2 of this administrative regulation.
- (2) A Class V MIH program license shall be issued only to the individual or organization named in the Mobile Integrated Healthcare Program License Application.
- (3) A Class V MIH program license shall not be transferable.
- (4) A Class V MIH program shall conspicuously display its license in a prominent public area at the Program's primary administrative office of operation.

(5) The following information shall be included on the license issued by the KBEMS office:

- (a) Operating name of the MIH program;
- (b) Physical location of the MIH program's primary administrative office of operation;
- (c) The number and physical location of satellite locations, if any, operated by the MIH program;
- (d) The license classification;
- (e) The level of service provided;
- (f) The number of equipment sets operated by the MIH program; and
- (g) The specific geographic area to be served by the MIH program.

(6) A MIH program license shall expire annually on December 31.

Section 4. Renewal of a Mobile Integrated Healthcare Program License. To renew a Class V MIH program license, the license holder shall:

- (1) Submit to the KBEMS office a completed Mobile Integrated Healthcare Program Renewal Application;
- (2) Pass an inspection conducted by the KBEMS office of the MIH program's premises, equipment, supplies, and records; and
- (3) Submit to the KBEMS office the fee established in 202 KAR 7:030.

Section 5. Inspections.

(1) Compliance with licensing pursuant to this administrative regulation shall be validated through on-site inspections of the MIH program by representatives or employees of the KBEMS office. The inspection shall include a:

- (a) Review of all equipment and supplies stocked; and
- (b) Review of personnel records, policy manuals, and other reports required to be maintained pursuant to 202 KAR Chapter 7.

(2) Each representative or employee of the KBEMS office shall have access to the MIH program's premises, records, and equipment during the hours that the MIH program operates.

(3) Notice of a regulatory violation identified during an inspection shall be transmitted in writing to the MIH program by the KBEMS office.

(4) Within ten (10) business days of receipt of notice of a regulatory violation, the MIH program shall submit a written plan for the elimination or correction of the regulatory violation to the KBEMS office.

(5) The plan shall specify the date by which the violations will be corrected.

(6) Within ten (10) business days following receipt of the plan, the KBEMS office shall notify the MIH program, in writing, whether the plan is accepted as providing for the elimination or correction of the violation.

(7) The KBEMS office may conduct follow-up visits to verify compliance with the plan.

(8) If a portion or all the plan is unacceptable:

- (a) The KBEMS office shall specify, in writing, why the plan is unacceptable; and
- (b) The provider shall modify or amend the plan and resubmit it to the KBEMS office within ten (10) business days after receipt of notice that the plan is unacceptable.

(9) Unannounced inspections of an MIH program may be conducted for a:

- (a) Complaint allegation;
- (b) Follow-up visit; or
- (c) Relicensing inspection.

Section 6. Unethical Conduct. The following acts shall be considered unethical conduct in the practice of providing MIH, and an MIH program or its EMS personnel shall be subject to disciplinary action and sanctions in accordance with KRS Chapters 311A and 13B for such conduct:

- (1) Failing to submit, amend, or modify a plan of correction to eliminate or correct a regulatory violation;
- (2) Failing to eliminate or correct a regulatory violation;
- (3) Falsifying an application for licensure;
- (4) Changing a license issued by the board without board approval;
- (5) Attempting to obtain or obtaining a license by:
 - (a) Fraud;
 - (b) Forgery;
 - (c) Deception;
 - (d) Misrepresentation; or
 - (e) Subterfuge;
 - (f) Providing false or misleading advertising;
 - (g) Falsifying, or causing to be falsified, reports regarding patient care or other reports provided to the KBEMS office;
 - (h) Providing an unauthorized level of service;
 - (i) Failing to provide the board or its representative with information upon request, or obstructing an investigation regarding alleged or confirmed violations of KRS Chapter 311A or 202 KAR Chapter 7;
 - (j) Issuing a payment on an invalid account or an account with insufficient funds to pay established fees, fines, or charges;
 - (k) Submitting fraudulent or misleading claims for reimbursement; or
 - (l) Failing to comply with local ordinances, federal statutes, KRS Chapter 311A, or 202 KAR Chapter 7.

Section 7. Public Notice of Negative Action. The KBEMS office shall publish on the KBEMS web site, or shall otherwise disseminate, the name of any MIH program that is fined, placed on probationary status, placed on restricted status, suspended, or that has had its license revoked.

Section 8. Management Requirements for Mobile Integrated Healthcare Programs.

- (1) All MIH programs shall maintain:
 - (a) An organizational chart that establishes lines of authority, including the designation of:
 1. An administrator responsible for ensuring compliance with KRS Chapter 311A and 202 KAR Chapter 7 during the daily operation of the MIH program; and
 2. A designee who shall serve in the absence of the administrator;
 - (b) Records and reports at the MIH program's primary administrative office, including:
 1. An original, electronic equivalent, or copy of all patient care records;
 2. An electronic copy of all completed patient care reports, which shall be maintained to ensure confidentiality and safekeeping for at least seven (7) years from the date on which the service was rendered or, in the case of a minor, at least three (3) years after the minor reaches the age of majority;
 3. Copies of patient care reports for the preceding twelve (12) months, which shall be accessible and be immediately available to the board, KBEMS office, or their representatives upon request; and
 4. Referrals for service received or made by the MIH program, which shall be maintained to ensure confidentiality and safekeeping for at least seven (7) years from the date on which the service was rendered or, in the case of a minor, at least three (3) years after the minor reaches the age of majority;
 - (c) Personnel files for each employee or volunteer who performs MIH activities on behalf of a MIH program. Personnel files shall be maintained for at least one (1) year following separation from employment. At a minimum, all personnel files shall contain:

1. A pre-employment and annual criminal background check administered by the Kentucky Administrative Office of the Courts; and
 2. A copy of the employee's valid KBEMS certification or licensure card, if any;
- (d) A written plan for providers to consult with online medical control for the patient population they are treating. This plan shall address at a minimum:
1. The availability of medical direction during hours of operation;
 2. The availability of medical direction during an emergency event;
 3. The provision of medical direction by a medical professional with a higher level of training or expertise; and
 4. Recommended actions if:
 - a. There is an equipment failure, a communication barrier, or other unusual circumstance; and
 - b. It is not possible to contact online medical direction;
- (e) A plan and records for the provision of continuing education for staff and volunteers, including:
1. A written plan for the method of assessing the continuing education needs of the MIH program's staff; and
 2. A coordinated plan to meet those needs, including a provision that all continuing education shall be provided either by a licensed EMS-TEI or in accordance with 202 KAR 7:601;
- (f) An infection control plan in accordance with 29 C.F.R. § 1910.1030;
- (g) Policies and procedures which address the assessment, planning, and care coordination services while providing MIH services. At a minimum such policies shall address:
1. Securing consent to obtain or release patient medical records to other healthcare providers;
 2. Coordination of care and reporting to discharge planners, home health agencies, primary care providers, and other organizations;
 3. Referral process to other outpatient care providers appropriate to address the needs identified in the patient care planning;
 4. Identification of patients eligible for services;
 5. Discontinuation of care and completion of care goals;
 6. Documentation requirements for each visit; and
 7. Patient communication and contact with the MIH program and its staff;
- (h) A written plan for the quality assessment of patient care and provider quality improvement, including a monthly review of patient care reports and evaluation of staff performance related to patient care. This plan shall address at a minimum:
1. Employee health and safety;
 2. Compliance with protocols and operating procedures;
 3. Additional training necessary for the patient care provider or providers;
 4. Equipment preventive maintenance programs; and
 5. A process for the resolution of customer complaints;
- (i) A written orientation program for all personnel, including at a minimum:
1. Validation of certification or license with KBEMS;
 2. A review of all agency policies, procedures, and protocols;
 3. Operational aspects of the equipment;
 4. Inspection and routine maintenance of equipment;
 5. Appropriate processes for disinfection of equipment;
 6. Local navigation and geographic orientation; and
 7. Completion of patient care reports and other documentation as established by the MIH program; and
- (j) Proof of professional liability malpractice insurance of a minimum of \$1,000,000.

(2) Each agency shall notify the board at least twenty-four (24) hours prior to the transfer of coverage, cancellation, lapse, or other cessation or change in professional liability malpractice insurance.

(3) Each MIH program shall verify valid staff certification or licensure as of the first day of the calendar year.

(4) If ceasing to operate, a MIH program shall provide the KBEMS office with the physical storage location of all patient care reports within five (5) business days of closure. The reports shall be maintained by the owner of the MIH program or a contracted third party to meet the retention requirements established in subsection (1)(b) of this section.

Section 9. Operating Requirements for Mobile Integrated Healthcare Programs.

(1) Each MIH program shall establish and publish its hours of operation for its geographic service area.

(2) Each MIH program shall retain staffing schedules for at least the previous twelve (12) months.

(3) A MIH program shall have a written scope of care policy which includes the types of services performed, limitations of response, and the types of medical teams provided.

(4) A MIH program shall promptly submit any changes to its written scope of care policy to the KBEMS office.

(5) Each MIH program shall post fee schedules in accordance with KRS 311A.032(1)(a) and 202 KAR 7:575.

Section 10. Staffing Requirement for Mobile Integrated Healthcare Programs. Each MIH program shall, at a minimum, be staffed by one (1) advanced practice paramedic licensed by the board and certified by the board as a community paramedic.

Section 11. Medical Directors of Mobile Integrated Healthcare Programs.

(1) Each MIH program shall have a medical director who meets the requirements established in 202 KAR 7:801.

(2) A MIH program shall notify the KBEMS office within twenty-four (24) hours of a decision to discontinue a medical director agreement by either MIH program or the medical director.

(3) If a MIH program is found to be operating without a medical director, the MIH program shall be provided emergency medical direction by the KBEMS medical advisor for a fee of \$100 per day for the first thirty (30) calendar days that the MIH program is without a medical director, and for a fee of \$500 per day thereafter.

Section 12. Equipment Requirements for Mobile Integrated Healthcare Programs.

(1) Each MIH program shall maintain evidence in the form of a letter that its medical protocols have been reviewed and approved by the board in accordance with KRS 311A.180. A hard copy or electronic equivalent of approved protocols shall be accessible to each provider throughout each patient encounter.

(2) A MIH program shall stock and maintain drugs and medications as required by the master drug list contained in protocols established in accordance with this section.

(3) Controlled drugs shall be stored in a locked storage box in a locked compartment that is accessible to emergency medical services personnel.

(4) A MIH program may maintain other supplies or equipment that are required to carry out its protocols as approved by the board in accordance with KRS 311A.180.

(5) All items with expiration dates that are maintained by a MIH program shall not be expired.

(6) A MIH program shall establish a master equipment and medication list by policy. All equipment and medication required by MIH program policy shall be fully operational and available for each patient encounter.

Section 13. Incorporation by Reference.

- (1) "Mobile Integrated Healthcare Program License Application", July 2024, is incorporated by reference.
- (2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Office of the Kentucky Board of Emergency Medical Services, 500 Mero Street, 5th Floor 5SE32, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.
- (3) This material may also be obtained at kbems.ky.gov.

JOHN R. HOLDER, Chair

APPROVED BY AGENCY: August 8, 2024

FILED WITH LRC: September 3, 2024 at 3 p.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall be held on November 27, 2024, at 1:00 p.m. ET at the Kentucky Board of Emergency Medical Services, 500 Mero Street, 5th Floor 5SE32, Frankfort, Kentucky 40601. Individuals interested in being heard at this hearing shall notify this agency in writing by 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 wishes to be heard 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 the proposed administrative regulation. Written comments shall be accepted through November 30, 2024. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

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