

**KENTUCKY BOARD OF EMERGENCY MEDICAL SERVICES
(Amendment)**

202 KAR 7:565. Clinical pilot programs.

RELATES TO: KRS 216B.020(2)(f), 311A.030, 311A.060, 311A.180, 311A.190
STATUTORY AUTHORITY: KRS 311A.020, 311A.025, 311A.030, 311A.035,
311A.165, 311A.170, 311A.175, 311A.190

CERTIFICATION STATEMENT: This is to certify that this administrative regulation complies with the requirements of 2025 RS HB 6, Section 8.

NECESSITY, FUNCTION, AND CONFORMITY: KRS 311A.020 requires the board to exercise all administrative functions in the regulation of the EMS system and the licensing of ambulance services and medical first response agencies, except those regulated by the Board of Medical Licensure or Cabinet for Health and Family Services. KRS 311A.035 authorizes the board to develop, monitor, and encourage other projects and programs that may be of benefit to emergency medical services in the Commonwealth. This administrative regulation establishes the process for agencies to submit clinical pilot programs and the standards for approval by the board.

Section 1.

(1) A clinical pilot program shall allow for the use of assessment techniques or clinical procedures beyond the regular scope of practice of emergency medical responders established in 202 KAR 7:701.

(2)

(a) A licensed agency seeking authorization for a clinical pilot program shall submit a Clinical Pilot Program Application ~~[written proposal]~~ that includes a:

1. Letter of intent;
2. Description of the type of pilot project;
3. General project description;
4. Patient Interaction Plan;
5. Staffing Plan;
6. Training and Education Plan;
7. Medical Direction and Quality of Improvement Plan;
8. Data Collection and Quantitative Reporting;
9. Written confirmation of research approval from an Institutional Review Board (IRB) within the Commonwealth ~~[Completed "Request for Expedited or Full Review" form located on pages 42 through 45 of the "Kentucky Community and Technical College System Human Subjects Review Board Handbook for Investigators: For the Protection of Human Subjects in Research," (6/2015)]~~, if applicable; and
10. Nonrefundable application fee of \$500.

(b) The applicant agency's administrator and medical director shall appear before the Medical Oversight Committee and subsequent meeting of the board to present the applicant agency's proposed pilot program for review or additional information.

(c) The Medical Oversight Committee shall review the applicant's proposal and assess on its individual merits if the project or program to be developed or implemented by the applicant is likely to benefit patients and providers of emergency medical services. The Medical Oversight Committee shall present its recommendation of approval or denial to the board at the next regularly scheduled board meeting.

(d) Upon approval of a clinical pilot program, the board shall develop quarterly report deadlines and data points for quarterly review by the Medical Oversight Committee.

1. The data points shall relate to the specific methods and goals identified in the applicant's proposal.
2. The reporting deadlines and data points shall be incorporated into a Memorandum of Understanding between the board and the applicant.
- (3) An individual certified or licensed by the board who successfully completes an approved educational pilot program in accordance with 202 KAR 7:601 shall perform the procedures relevant to the training and education received in the pilot program subject to protocols established by the medical director and approved by the board in accordance with KRS 311A.180.
- (4) The board may limit:
 - (a) The geographic area or service location where the procedure is performed; and
 - (b) The performance of the procedure subject to a:
 1. Specific and defined event;
 2. Disaster; or
 3. Designated directive.
- (5) The board shall authorize the use of physicians or other medical professionals to supervise and monitor the training and education of providers involved in a pilot program.
- (6) The board may restrict actions that involve the performance of an invasive procedure or the administration of medication subject to:
 - (a) Physician or medical director oversight; or
 - (b) The use of protocols that have been submitted to the board for review and approved by the state medical advisor and the board in accordance with KRS 311A.180.
- (7) The office of the board shall retract the approval of any Clinical Pilot Program immediately if:
 - (a) The agency is in violation of any provisions approved by the board, including data submission requirements; or
 - (b) There is evidence the assessment technique or procedure has caused physical or psychological harm to a patient.
- (8) Violation of any provision of a Clinical Pilot Program shall be grounds for discipline in accordance with KRS Chapter 311A.060.

Section 2. Public Notice of Negative Action. The board office shall publish on the KBEMS web site or similar publication of the board the name of any licensed agency that is fined, placed on probationary status, placed on restricted status, suspended, or had a license revoked.

Section 3. Incorporation by Reference.

- (1) "Clinical Pilot Program Application", (5/2025), is incorporated by reference. [~~"Kentucky Community and Technical College System Human Subjects Review Board Handbook for Investigators: For the Protection of Human Subjects in Research", (6/2015), is incorporated by reference.~~]
- (2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Emergency Medical Services, 500 Mero Street, 5th Floor, 5SE32, Frankfort, Kentucky 40601 [~~118 James Court, Suite 50, Lexington, Kentucky 40505~~], Monday through Friday, 8 a.m. to 4:30 p.m.
- (3) This material is also available on the board website at: kbems.ky.gov.

JOHN R. HOLDER, Chair

APPROVED BY AGENCY: April 30, 2025
FILED WITH LRC: May 21, 2025 at 2:36 p.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall be held on August 22, 2025, 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 August 31, 2025. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

CONTACT PERSON: John K. Wood, counsel for the Kentucky Board of Emergency Medical Services, 163 East Main Street, Suite 200, Lexington, Kentucky 40507, phone (859) 225-4714, email administrativeregulations@wgmfirm.com.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: John K. Wood

(1) Provide a brief summary of:

(a) What this administrative regulation does:

KRS 311A.035 authorizes the board to develop, monitor, and encourage other projects and programs that may be of benefit to emergency medical services in the Commonwealth. This administrative regulation establishes the process for agencies to submit clinical pilot programs and the standards for approval by the board.

(b) The necessity of this administrative regulation:

This administrative regulation is necessary to establish processes and standards for clinical pilot programs.

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

This administrative regulation conforms to the content of KRS 311A.035(5) by establishing processes and standards for clinical pilot programs and to develop, monitor, and encourage the same.

(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 KRS 311A.035(5) by establishing the process for agencies to submit clinical pilot programs and the standards for approval by the board.

(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 removes outdated references to the Kentucky Community and Technical College.

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

This amendment is necessary because the Board is no longer attached to the Kentucky Community and Technical College System.

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

This amendment conforms to the content of KRS 311A.035(5) by revising the process for agencies to submit clinical pilot programs.

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

This amendment will assist in the effective administration of KRS 311A.035(5) by removing outdated provisions.

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

This administrative regulation will affect any EMS agency wishing to create a clinical pilot program.

(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:

Agencies wishing to create a clinical pilot program will be required to submit the new Pilot Program Application and comply with the remaining processes and requirements established in this amendment.

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

This administrative regulation establishes a \$500 fee for applying for a clinical pilot program.

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

Affected entities will benefit from the removal of outdated provisions in this administrative regulation.

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

(a) Initially:

Other than administrative costs, there will be no costs to the Board in implementing this administrative regulation.

(b) On a continuing basis:

Other than administrative costs, there will be no costs to the Board in implementing this administrative regulation.

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

The Kentucky Board of Emergency Medical Services is a state agency that receives its annual budget from the state government.

(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 will be necessary to implement this amendment.

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

This administrative regulation establishes a \$500 application fee, which has not been changed in this proposed amendment.

(9) TIERING: Is tiering applied?

Tiering is not applied to this administrative regulation because the amendment applies to all agencies seeking to create a clinical pilot program.

FISCAL IMPACT STATEMENT

(1) Identify each state statute, federal statute, or federal regulation that requires or authorizes the action taken by the administrative regulation:

KRS 311A.035 authorizes the board to develop, monitor, and encourage other projects and programs that may be of benefit to emergency medical services in the Commonwealth. This administrative regulation establishes the process for agencies to submit clinical pilot programs and the standards for approval by the board.

(2) State whether this administrative regulation is expressly authorized by an act of the General Assembly, and if so, identify the act:

KRS 311A.035, last amended by 2022 Ky. Acts ch. 126, sec. 5, authorizes the board to develop, monitor, and encourage other projects and programs that may be of benefit to emergency medical services in the Commonwealth. This administrative regulation establishes the process for agencies to submit clinical pilot programs and the standards for approval by the board.

(3)(a) Identify the promulgating agency and any other affected state units, parts, or divisions:

This amendment is promulgated by the Kentucky Board of Emergency Medical Services.

(b) Estimate the following for each affected state unit, part, or division identified in (3)(a):

1. Expenditures:

For the first year:None

For subsequent years:None

2. Revenues:

For the first year:None

For subsequent years:None

3. Cost Savings:

For the first year:None

For subsequent years:None

(4)(a) Identify affected local entities (for example: cities, counties, fire departments, school districts):

Any city or county emergency ambulance service seeking to operate a clinical pilot program.

(b) Estimate the following for each affected local entity identified in (4)(a):

1. Expenditures:

For the first year:None

For subsequent years:None

2. Revenues:

For the first year:None

For subsequent years:None

3. Cost Savings:

For the first year:None

For subsequent years:None

(5)(a) Identify any affected regulated entities not listed in (3)(a) or (4)(a):

Any emergency medical services, first response agencies, or mobile integrated health care programs seeking to operate a clinical pilot program.

(b) Estimate the following for each regulated entity identified in (5)(a):

1. Expenditures:

For the first year:None

For subsequent years:None

2. Revenues:

For the first year:None

For subsequent years:None

3. Cost Savings:

For the first year:None

For subsequent years:None

(6) Provide a narrative to explain the following for each entity identified in (3)(a), (4)(a), and (5)(a)

(a) Fiscal impact of this administrative regulation:

No fiscal impact is anticipated as a result of this administrative regulation, other than the existing costs of operating a clinical pilot program.

(b) Methodology and resources used to reach this conclusion:

This amendment does not increase any fees and is not otherwise expected to have a fiscal impact.

(7) Explain, as it relates to the entities identified in (3)(a), (4)(a), and (5)(a):

(a) Whether this administrative regulation will have a "major economic impact", as defined by KRS 13A.010(13):

This administrative regulation will not have a major economic impact.

(b) The methodology and resources used to reach this conclusion:

This amendment does not increase any fees and is not otherwise expected to have a fiscal impact.