

## **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

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. 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 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. 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) "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, 118 James Court, Suite 50, Lexington, Kentucky 40505, Monday through Friday, 8 a.m. to 4:30 p.m. (44 Ky.R. 1747; eff. 5-4-2018.)