**Section 515.360 Approval of Additional Pilot Programs, Medications, and Equipment**

a) All pilot programs, medications, and equipment, other than those covered by the national EMS education standards, as modified by the Department, for each level of licensure, must be approved by the Department in accordance with subsections (b), (c) and (d) before being used in a System.

b) To apply for approval for a pilot program or to add medications and/or equipment, the EMS MD shall submit to the Department documentation covering the following:

1) The education program for all additional psychomotor skills and the number of continuing education hours;

2) A curriculum for the pilot program or each additional medications, psychomotor skill, equipment or device, which includes at least the following (as applicable):

A) Objectives;

B) Methods and materials;

C) Content, which shall include, but not be limited to, usage, complications, adverse reactions, and equipment maintenance and use;

D) Evidence-based standards and guidelines relevant to the proposal; and

E) Evaluation of learning; and

3) New written standing orders.

c) Upon receipt of the application from the System, the Office of Preparedness and Response (OPR) Medical Director or Division Chief or his or her designee shall either approve the program or the medication or equipment, approve the program, medication or equipment on a conditional basis, or disapprove the program, medication or equipment. The OPR Medical Director or Division Chief or designee's decision shall be based on a review and evaluation of the documentation submitted under subsection (b); the application of technical and medical knowledge and expertise; consideration of relevant literature and published studies on the subject; and whether the program, medication or equipment has been reviewed or tested in the field. The OPR Medical Director or Division Chief may seek the recommendations of medical specialists or other professional consultants to determine whether to approve or disapprove the specific medication or medications or equipment.

d) The OPR Medical Director or Division Chief or designee shall consider whether the medications and equipment may be used safely and with proper education by the pre-hospital care provider and shall disapprove any program, medications or equipment that he or she finds are generally unsafe or dangerous in the pre-hospital care setting.

e) When a program, medication or equipment is approved on a conditional basis, the System shall submit to the Department, on a quarterly basis (January 1, April 1, July 1 and October 1) the following information:

1) Indications for use;

2) Number of times used;

3) Number and types of complications that occurred;

4) Outcome of patient after use of medication or equipment; and

5) Description of follow-up actions taken by the System on each case in which complications occurred.

f) When a death or complication that results in a deterioration of a patient's condition occurs, involving a program, medication or equipment approved on a conditional basis, the System shall notify the Department within three business days, followed by a written report of the situation submitted to the Department within 10 business days.

g) Failure of the System to submit the information required under subsection (e) shall be considered as a basis for withdrawal of approval of the program, medication or equipment on a conditional basis. Failure of the System to notify the Department as required under subsection (f) shall be considered as a basis for withdrawal of approval of the program, medication or equipment on a conditional basis.

h) The OPR Medical Director or designee shall evaluate the information submitted under subsection (e) and any notification required under subsection (f). The Department will notify the System that a program, medication or equipment is disapproved and may no longer be performed on a conditional basis when the evaluation of the information submitted pursuant to this subsection (h) indicates that the safety of the medication or equipment has not been established for use in the pre-hospital setting.

i) An EMS MD shall not approve EMS Personnel to implement a program or use new medications or equipment unless that individual has completed the System-approved education program and examination, and has demonstrated the required knowledge and skill to use that intervention safely and effectively.

j) An EMS MD shall not be required to provide education on new interventions to EMS Personnel who will not be using the new interventions.

k) The Department may share best practice models with proven efficacy with the EMS System EMS MDs.

(Source: Amended at 48 Ill. Reg. 16159, effective November 1, 2024)