

906 KAR 1:140. Validation and complaint investigation procedures for deemed hospitals.

RELATES TO: KRS 216.2925, 216.530, 216B.010, 216B.015, 216B.040, 216B.042, 216B.045-216B.055, 216B.075, 216B.105-216B.131, 216B.990

STATUTORY AUTHORITY: KRS 216B.185

CERTIFICATION STATEMENT:

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.185 requires that the cabinet promulgate the necessary administrative regulations to implement the licensing validation process for hospitals deemed in compliance with licensure requirements. This administrative regulation implements the licensing validation process and establishes a procedure for investigating complaints at deemed hospitals.

Section 1. Definitions.

- (1) "CMS" means the Centers for Medicare and Medicaid Services.
- (2) "Deemed hospital" means a hospital that is deemed to be in compliance with licensure requirements pursuant to the provisions of KRS 216B.185.
- (3) "Inspecting agency" means the Cabinet for Health Services, Office of the Inspector General.
- (4) "State licensure standard" means an individual requirement contained within the operations and services regulation of a deemed hospital.

Section 2. Licensure Validation Inspection.

- (1) On an annual basis the inspecting agency shall select a minimum of five (5) percent and no more than ten (10) percent of the total number of deemed hospitals and conduct an on-site inspection to validate that state licensure standards are met.
- (2) A deemed hospital that has received a CMS certification validation survey in the previous twelve (12) months shall not be selected for a licensure validation inspection.
- (3) A deemed hospital that is selected to receive a licensure validation inspection shall be notified of the inspection at least seven (7) days before the scheduled inspection date.
- (4) The inspecting agency shall conduct validation surveys in accordance with the provisions contained in Section 4 of this administrative regulation.

Section 3. Complaint Investigation Inspection.

- (1) If the inspecting agency receives a complaint or becomes aware from another state agency or through the media that a deemed hospital may not be in compliance with a state licensure standard, the inspecting agency shall conduct an investigation of the alleged noncompliance.
- (2) Complaint investigations shall be unannounced and conducted in accordance with the procedures in Section 4 of this administrative regulation.

Section 4. Procedures for Conducting Validation and Complaint Investigations of Deemed Hospitals.

- (1) If the inspecting agency determines, as a result of an on-site licensure validation or complaint investigation inspection, that a hospital is not in compliance with a state licensure standard:
 - (a) At the conclusion of the of the on-site inspection, the survey staff of the inspecting agency shall conduct an exit conference to discuss preliminary findings with the hospital administrator or designee;
 - (b) The inspecting agency shall inform the hospital in writing of the violation of the state licensure standard within ten (10) days of the inspection; and
 - (c) The hospital shall submit to the inspecting agency, within ten (10) days of receipt of the written notice, a written plan for the correction of the violation;
 1. The plan shall specify:

- a. The date by which the violation shall be corrected;
 - b. The specific measures utilized to correct the violation; and
 - c. The specific measures that will be utilized to ensure the violation will not reoccur.
 2. Following a review of the plan, the inspecting agency shall notify the hospital in writing of the acceptability of the plan.
 3. If a portion or all of the plan is unacceptable:
 - a. The inspecting agency shall specify the reasons for the unacceptability; and
 - b. The hospital shall modify or amend the plan and resubmit it to the inspecting agency within ten (10) days.
 4. Upon receipt of an acceptable plan of correction, the inspecting agency may conduct a follow-up on-site inspection to ensure that the violation has been corrected.
- (2) The hospital shall lose its status as a deemed hospital if, as a result of the on-site licensure validation or complaint investigation inspection, the inspecting agency determines that a hospital has:
- (a) A single violation of a state licensure standard of sufficient severity that the violation poses a substantial risk to patient care or patient safety; or
 - (b) A substantial number of violations of state licensure standards.
- (3) The hospital shall regain its deemed status when the inspecting agency determines that the violation or violations have been corrected.
- (906 KAR 001:140. 29 Ky.R. 3002; 30 Ky.R. 870; eff. 10-15-2003; Crt eff. 1-11-2019; Crt eff. 11-24-2025.)