

DATE: August 5, 2019

SUBJECT: Guidance for innovative hospital models

ISSUE

Identify the regulatory authority for the Department of Health (Department) to approve applicants' requests for hospital licensure and provide information regarding the application and licensing process for an innovative hospital model.

BACKGROUND

Several applicants for hospital licensure have approached the Department with innovative plans for facilities that offer fewer services than existing hospitals. An example of an innovative hospital model would be a full emergency department without 24/7 surgical services.

As the regulator, the Department is responsible for ensuring appropriate levels of patient safety, quality of care and patient access. While we are cognizant of our role as the regulator, the Department does not want to prevent innovative ways to provide patient care in a changing health care environment.

A facility applying to be licensed as a hospital must meet the statutory definition of a hospital, which includes "being established for the purpose of providing services to inpatients" and meeting all applicable regulatory requirements.

APPLICATION PROCESS:

The Department has concluded that innovative hospital models can be licensed under the current statutory and regulatory scheme. Facilities seeking licensure should use the following guidance when applying for licensure:

The facility must request an application from the Department, pursuant to 28 Pa. Code § 101.43. The facility shall complete the application and submit a plan review. In addition to all documentation currently required, the plan review for an innovative hospital model should include the following:

1. A description of the innovative model and how the innovation promotes efficient delivery of services in the area, increases quality of care delivered and increases access by patients; and
2. A statement that the facility will meet CMS guidelines and requirements and a description of how the specific guidelines will be met.

A facility with an innovative hospital model should review the below guidance on "Requirements for Licensure" when completing its application.

REQUIREMENTS FOR LICENSURE

The Health Care Facilities Act (35 P.S. §448.801 – 448.904b) provides the Department with the authority to license health care facilities and to promulgate regulations necessary to carry out such licensure. A facility seeking licensure must show that it meets the Department’s regulatory requirements to be issued a license. The Department has provided the below guidance relating to specific requirements under the Department’s regulations that may be useful to applicants with an innovative hospital model.

- The Department requires the facility to meet the requirements of 28 Pa. Code § 101.31 with the noted guidance:
 - **§ 101.31. Hospital requirements:** A hospital shall have all of the following:
 - (1) An organized governing body;
 - (2) A chief executive officer;
 - (3) An organized medical staff;
 - (4) An organized nursing staff;
 - (5) Medical services, continuous¹;
 - (6) Nursing services, continuous;
 - (7) Permanent on-site facilities for the care of patients 24 hours a day;
 - (8) A hospital-wide infection control program;
 - (9) Minimum on-site clinical provisions as follows:
 - (i) Inpatient care areas equipped with hospital furnishings.
 - (ii) Nursing care units.
 - (iii) Diagnostic and treatment areas²

¹ A facility with an innovative hospital model will need to provide documentation evidencing its ability to provide continuous medical services. If the facility intends to satisfy this requirement through transfer agreements, it must include arrangements with all neighboring hospitals where a patient would foreseeably be sent for continuation of medical care which cannot be safely provided by the facility. The facility must also have a policy that specifically states that the facility will comply with all EMTALA requirements prior to the transfer of a patient. The Department reserves the right to reject an application if a facility is not able to secure an acceptable transfer agreement with all neighboring hospitals or if the Department determines that the distance and/or time of transfer is too great to be considered continuous care.

- (iv) Supplies and equipment to meet the medical and nursing needs of the patients within the scope of the services provided.
- (v) Pharmaceutical services in compliance with Chapter 113 (relating to pharmacy services).
- (vi) Facilities for the sterilization of equipment and supplies.
- (vii) Treatment equipment for drug, blood, and parenteral fluid administration and for performance of medical or surgical nursing procedures.
- (viii) Treatment equipment for the management of common medical or surgical, or both, emergencies, including facilities for cardio-pulmonary resuscitation³.
- (ix) Medical records services.
- (x) Provision for medical social work services in compliance with Chapter 121 (relating to social work services).
- (xi) Professional library services in compliance with Chapter 145 (relating to professional library services)⁴.
- (xii) Provision for therapeutic diets; and

(10) Minimum supportive capabilities or facilities as follows:

² A facility with a full emergency department without 24/7 surgical services must post a list of services provided at the facility and satisfy the following minimum services to comply with this subsection:

- (1) Inpatient beds: Minimum of ten inpatient beds, with at least one room being an airborne infection isolation room.
- (2) Treatment rooms: Minimum of ten treatment rooms in the emergency department to include:
 - One pediatric exam/treatment
 - One patients of size/large treatment
 - One trauma/resuscitation
- (3) Psychiatric room: Minimum of one room, whether in the emergency department or the inpatient unit, shall be provided for psychiatric care. This room is in addition to the number of rooms required in (1) and (2).
- (4) Onsite imaging services to include:
 - General Radiography
 - Computed Tomography (CT)
 - Magnetic Resonance Imaging (MRI)

³ A facility must be able to demonstrate that it has the requisite equipment to adequately provide care for the health care services it delivers, including complying with all EMTALA requirements.

⁴ A facility may provide library services electronically or online.

- (i) A safe, structurally sound, habitable, sanitary, fire-resistant physical plant designed and equipped specifically for the delivery of contemporary forms of hospital care.
- (ii) Facilities to provide adequate heat, light, ventilation, potable water, sewage disposal, electrical power, internal and external communications, and emergency utility services.
- (iii) Sanitary garbage, trash, and waste disposal.
- (iv) Internal and external environmental sanitation services.
- (v) Sanitary laundry services for hospital garments and linens.
- (vi) Sanitary hospital dietary services.
- (vii) An internal fire and disaster plan, fire alarm system and evacuation plan.
- (viii) Scheduled general and preventive maintenance services for building, services and biomedical equipment.
- (ix) Participation with community agencies in the establishment of the role of the hospital in event of external disasters⁵.
- (x) Capability for obtaining police and fire protection, emergency transportation, grounds-keeping and snow removal.
- (xi) Personnel recruitment, training and continuing education.
- (xii) Business management capability.
- (xiii) Short- and long-range planning capability.
- (xiii) Fiscal services to assure continuity of operation under both normal and an emergency conditions.
- (xiv) Comprehensive policies and standards for assuring the safety of patients, employees and visitors and for protection against malpractice and negligence.

The Department shall use this guidance when reviewing an application from a facility with an innovative hospital model. Please note the Department may need to complete additional surveys to determine an applicant's statutory and regulatory compliance.

⁵ A facility must meet CMS guidelines and requirements to satisfy this subsection.