



## CRITERIA AND GUIDANCE TO IMPLEMENT AN OUTPATIENT EMERGENCY DEPARTMENT

March 2022

### **Background**

The Pennsylvania Department of Health (Department) is charged with overseeing health care services and facilities to ensure access to high quality care and encouraging innovation and continuous development of improved methods of health care in the Commonwealth. In carrying out these duties, the Department continues to monitor advancements in technology and care models to support an effective and efficient health care system.

Over the last several years, the Department has engaged in discussions with hospitals and health systems to address the ongoing interest in the Commonwealth to offer emergency department services with reduced or no onsite inpatient care and surgical services. To that effect, in 2019, the Department provided [guidance](#) to hospitals to offer minimal inpatient services while retaining an emergency department (ED). This innovative hospital model has proven to be a viable alternative to many facilities and will continue to be an option for providers seeking to offer acute care services in a smaller footprint. Building on the progress of the innovative hospital model, the Department has continued to monitor advancements in the provision of emergency hospital services across the country. Through that monitoring, the Department has recognized that meeting those minimum requirements in hospitals whose inpatient census averages less than 10 on a daily basis can be burdensome and additional alternatives may be helpful to preserve access to care.

While the Department does not have the authority under the Health Care Facilities Act (HCFA) to license a facility as a hospital that does not offer any inpatient services<sup>1</sup>, the Department is authorized to establish criteria to allow a hospital to operate multiple clinical facilities.<sup>2</sup> These separate or distinct clinical facilities may be referred to as campuses, off-campus facilities, satellite locations, or outpatient locations. The purpose of this guidance document is to communicate the criteria established by the Department for a hospital to operate a clinical facility or location where emergency services are offered at the location, but there are no inpatient or surgical services onsite. This care model is intended to supplement existing health care options in the Commonwealth and does not replace the innovative hospital model, now known as the micro-hospital model and as updated in March 2022.

The Centers for Medicare & Medicaid Services (CMS) has allowed certified hospitals to be reimbursed for emergency department services offered at an outpatient location since [2008](#). CMS also authorized free-standing EDs to participate in Medicare and Medicaid during the COVID-19 Public Health Emergency. As of 2015, 32 states have [permitted](#) hospitals to operate outpatient

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<sup>1</sup> See 35 P.S. § 448.802a, which requires a “hospital” to be established for the purpose of providing inpatient care.  
<sup>2</sup> 28 Pa. Code § 101.191.



emergency departments (OEDs).<sup>3</sup>

The Department is authorizing the operation of OEDs as a means to preserve and create access to health care in rural areas. In jurisdictions where OEDs and freestanding EDs are operating, studies have shown that when the model is not restricted to areas where the population does not have easy access to emergency care, OEDs and freestanding EDS are placed in high-income, urban areas with fewer racial and ethnic minorities and a favorable payer mix.<sup>45</sup> For this reason, the Department has determined that limiting the authorization to OEDs in rural areas will most effectively preserve and create access to emergency care for Pennsylvanians that need it most.

This model has proven to be an effective alternative in areas where critical access hospitals were struggling to remain open, such as Arizona.<sup>6</sup> The model is also consistent with national efforts. In 2020, as part of the Consolidated Appropriations Act, 2021, Congress established a “Rural Emergency Hospital” CMS designation to begin in 2023. This change will allow eligible rural hospitals to enroll as a Rural Emergency Hospital, receive increased reimbursement for care, and operate independently of inpatient providers.<sup>7</sup> For these reasons, the Department is authorizing the operation of OED in accordance with this guidance.

## **Definitions**

For purposes of this guidance document, the following terms will be defined as described in this section unless the context clearly indicates otherwise.

- A “hospital” is jointly the main licensed hospital, its campuses and outpatient locations.
- A “main licensed hospital” is the location where the hospital license is held.
- “Outpatient locations” are the locations offering outpatient services that are included under the license of the main licensed hospital but not located on its grounds.
- “Outpatient emergency department” or “OED” is an outpatient location of a hospital that offers only emergency services and is not located on the grounds of a main licensed hospital.

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<sup>3</sup> Alexander, Alexander J., et al. “Freestanding Emergency Departments: What is Their Role in Emergency Care?” *Annals of Emergency Medicine* (2019), vol. 74 no. 3, pp. 325-331. doi: j.annemergmed.2019.03.018

<sup>4</sup> Williams, J. Dunc, et al. “Estimated Costs of Rural Freestanding Emergency Departments.” *NC Rural Health Research Program*, Nov. 2015, [https://www.shepscenter.unc.edu/wp-content/uploads/dlm\\_uploads/2015/11/Rural-Freestanding-ED.pdf](https://www.shepscenter.unc.edu/wp-content/uploads/dlm_uploads/2015/11/Rural-Freestanding-ED.pdf).

<sup>5</sup> Schuur, Jeremiah D., et al. “Where Do Freestanding Emergency Departments Choose to Locate? A National Inventory and Geographic Analysis in Three States” *Annals of Emergency Medicine* (2016) <https://scholar.harvard.edu/files/cutler/files/1-s2.0-s0196064416301998-main.pdf>.

<sup>6</sup> Alexander, Alexander J., et al. p 329.

<sup>7</sup> Cook, Emily J., et al. “Congress Establishes New Medicare Provider Category and Reimbursement for Rural Emergency Hospitals.” *National Law Review* (2021), vol. XI, no. 214. <https://www.natlawreview.com/article/congress-establishes-new-medicare-provider-category-and-reimbursement-rural>



## **Eligibility Criteria**

To be authorized to operate an OED, a hospital shall meet the following criteria:

- The main licensed hospital shall offer general acute care services.
- The OED shall be included as an outpatient location under the license of the hospital and must be located within a 35 mile radius of the main licensed hospital.
- The OED shall be located in a rural area. For purpose of this guidance, a “rural area” is any area not included in an “urbanized area” by the [U.S. Census Bureau](#) based on the 2010 decennial census.
  - The U.S. Census Bureau’s [mapping tool](#) can be used to determine eligibility. All areas that are not in an urbanized area (blue areas) are eligible locations for an OED. Areas designated as an “urban cluster” constitute a rural area for purposes of this guidance.
- The hospital shall continue to meet the statutory definition of a “hospital” as defined in the HCFA by devoting 51% or more of its total beds to inpatient care.
- The main licensed hospital and the OED shall be under common legal ownership.

## **Guidance on Compliance with General Hospital Requirements in the OED**

**Hospitals are required to maintain full or substantial compliance with all applicable regulations. The purpose of this document is to provide guidance to hospitals on compliance with the regulations in the context of a hospital with an OED and is not an exhaustive list of regulatory requirements. Please contact your Division of Acute and Ambulatory Care (DAAC) Field Office if you have questions that are not addressed by the guidance provided below.**

- The OED shall be fully integrated with the main licensed hospital. Fully integrated means:
  - Medical staff practicing at the OED are members of the medical staff of the main licensed hospital and maintain compliance with 28 Pa. Code Ch. 107 (relating to medical staff).
  - Nursing personnel at the OED are part of the organized nursing service of the main licensed hospital and maintain compliance with 28 Pa. Code Ch. 109 (relating to nursing services).
  - Medical records of patients seen at the OED are part of the main licensed hospital’s medical record system and meet the requirements of 28 Pa. Code Ch. 115 (relating to medical record services).
  - The OED is included in the main licensed hospital’s hospital-wide infection prevention and control program and reflected in the main licensed hospital’s infection control plan in



- accordance with Section 403 of the Medical Care Availability and Reduction of Error (MCARE) Act<sup>8</sup>.
- The OED is included in the main licensed hospital's emergency plan as set forth at 28 Pa. Code Ch. 151 (relating to fire, safety, and disaster services) and 42 CFR 483.73 (relating to conditions of participation: emergency preparedness).
  - The hospital shall demonstrate that the OED independently<sup>9</sup> satisfies the following requirements at all times:
    - A minimum of ten treatment rooms in the OED. The treatment rooms shall be staffed and equipped to meet the needs of patients presenting at the OED. The rooms shall, at a minimum, be comprised of:
      - An obstetrics/gynecology examination/treatment room.
      - A pediatric examination/treatment room.
      - A trauma/emergency stabilization treatment room.
      - A psychiatric/behavioral health examination/treatment room.
    - Imaging services are available on-site, including, at a minimum, general radiography (X-ray) and Computer Tomography (CT). Imaging services shall be offered in accordance with 28 Pa. Code Ch. 127 (relating to radiology services).
    - Standard medications, parenteral fluids, plasma substitutes and surgical supplies are on hand for immediate use in treating life-threatening conditions. Additional equipment and medications needed to support the OED are available on-site or can be readily procured.
    - Sterile equipment and supplies are available on-site to meet the needs of patients. If the OED does not have facilities for sterilization on-site, sterile, disposable equipment and supplies may be used.
    - Laboratory services are available on-site to meet the needs of patients.
    - Treatment equipment for drug, blood, and parenteral fluid administration and for the performance of medical procedures are available on-site.
    - Treatment equipment for the management of common medical emergencies, including facilities for cardio-pulmonary resuscitation, are available on-site.
    - Supplies for patient nutrition/nourishment are available on-site.
  - The hospital shall demonstrate that the OED has ongoing access to the following supportive capabilities, facilities, and services, though compliance may be evidenced through the OED's participation in hospital-wide resources or services:
    - Sanitary garbage, trash, and waste disposal.
    - Sanitary location for dietary services.
    - Access to social work services in accordance with 28 Pa. Code Ch. 121 (relating to social work services).

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<sup>8</sup> 40 P.S. § 1303.403.

<sup>9</sup> The OED cannot rely on services, rooms, equipment, staff, or supplies at the main licensed hospital to satisfy these requirements.



- Sanitary laundry services for hospital garments and linens.
- The hospital has developed and implemented methods for safe transfer of patients requiring services not provided at the OED, which shall include:
  - The development and implementation of transfer policies and procedures, including intra-hospital transfers. Policies and procedures and their implementation shall be in accordance with Emergency Medical Treatment and Labor Act (EMTALA), 42 U.S.C. §§ 1395dd(a)-(i).
  - Transfer agreements with all nearby hospitals that are able to render care to patients who are likely to require services of a nearby hospital because the services cannot be provided by the OED or the main licensed hospital.
  - A prohibition on transfers that jeopardize the health or safety of a patient or cause an unnecessary delay in care.

### **Guidance on Compliance with Chapter 117 (relating to emergency services) in the OED**

The hospital must demonstrate that the OED independently maintains compliance with emergency service requirements as set forth at 28 Pa. Code Ch. 117 (relating to emergency services) at all times, including:

- Ensuring services are available 24 hours a day, 7 days a week.
- Development and implementation of policies and procedures pursuant to 28 Pa. Code 117.41 (relating to emergency patient care) that reflect the unique circumstances of the OED.
- Ensuring at least one physician and one registered nurse qualified by experience in emergency care are on-site at all times and additional medical staff, practitioners, and nursing staff are on-site as needed to meet the needs of patients.

### **Guidance on Compliance with Chapter 153 (relating to initial construction and continuing operating standards) in the OED**

All emergency departments, including OEDs, are classified by the Department as healthcare occupancies because they are used for the provision of treatment and care to patients 24 hours a day, 7 days per week. As such, all OEDs shall comply with the healthcare occupancies requirements as set forth in NFPA 101, 2012 Life Safety Code.

An OED that had previously operated as an emergency department of a hospital and was determined to be in compliance with the Department's regulations at that time will be deemed in compliance with subsequent editions of the Facility Guidelines Institute, *Guidelines for Design and Construction of Hospitals (Guidelines)*, unless the space has not been occupied or used for one calendar year or more.

Alterations, renovations, and construction of an OED, including transition of any space or location that had not previously been determined to be in compliance with the Department's regulations for



the specific use shall comply with 2018 edition of the *Guidelines*.

**Development of an OED**

A hospital that intends to operate an OED shall meet notification requirements as set forth at 28 Pa. Code § 51.3 (relating to notifications).