

CRITERIA AND GUIDANCE TO IMPLEMENT AN OUTPATIENT EMERGENCY DEPARTMENT

Updated January 2023¹

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 for many facilities and will remain 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.

In March 2022, the Department, pursuant to its authority under Section 101.191 of the Department's Hospital Regulations, 28 Pa. Code § 101.191, established criteria for hospitals to offer emergency services at an outpatient location with no other inpatient or surgical services onsite. These locations are known as outpatient emergency departments or OEDs. The Department authorized the operation of OEDs as a means to preserve and create access to health care in rural areas. This authorization was consistent with Federal certification requirements, as 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 had [permitted](#) hospitals to operate OEDs.²

In September 2022, after the initial release of the Department's OED guidance, the Department again engaged with stakeholders, including hospitals and members of the General Assembly, to further discuss the criteria established for location of OEDs. As a result of those discussions, the Department updated the guidance to make requested changes related to eligible locations to operate an OED. Notably, OEDs were no longer limited to rural areas but could not be located

¹ Text in red font indicates a substantive change from the Department's September 2022 *Guidance to Implement an OED*.

² 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

within 35 miles of an existing emergency department. As with the prior authorization of OEDs, this care model was intended to supplement existing health care options in the Commonwealth and did not replace the innovative hospital model, now known as the micro-hospital model and as updated in March 2022.

Over the last several months, the Department, along with stakeholders, have continued to assess the effectiveness of the OED model as means to preserve access to high-quality health care. Also, during that time, CMS published its final rule for rural emergency hospitals (REH), with the certification becoming available on January 1, 2023.³ While the General Assembly has not yet established REH as a health care facility type in the Commonwealth, the Department is authorizing hospitals that would be eligible for the REH certification to transition to an OED without a catchment area. Nationwide, at least 120 rural hospitals have closed since 2010 and over 450 hospitals are considered vulnerable for closure.⁴ In Pennsylvania, 22% of rural hospitals are considered vulnerable.⁵ Allowing small rural hospitals to transition to an OED without a catchment area will give those hospitals who are unable to maintain inpatient beds an alternative to closure and will help preserve access to emergency care in Pennsylvania's rural communities.

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 “catchment area” is the area surrounding an OED.
- A “Critical Access Hospital” or “CAH” is a hospital with no more than 25 inpatient beds that was certified by the Centers for Medicare and Medicaid Services (CMS) as a CAH as of December 27, 2020.
- A “hospital” is jointly the main licensed hospital, its campuses and outpatient locations, under common legal ownership.
- A “main licensed hospital of the OED” is the location where the hospital license is held.
- An “outpatient location” is a location offering only outpatient services that is included under the license of the main licensed hospital but not located on the grounds of the main licensed hospital.
- An “outpatient emergency department” or “OED” is an outpatient location of a hospital under common legal ownership that offers emergency services and is not located on the grounds of a main licensed hospital.

³ 2023 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System Final Rule, CMS-1772-FC. Available at <https://www.govinfo.gov/content/pkg/FR-2022-11-23/pdf/2022-23918.pdf>.

⁴ “The Rural Health Safety Net Under Pressure.” The Chartis Center for Rural Health (Feb. 2020). Available at <https://www.chartis.com/sites/default/files/documents/Rural%20Hospital%20Vulnerability-The%20Chartis%20Group.pdf>.

⁵ Id.

- A “small rural hospital.” A hospital located in a rural area as defined in Section 1886 (d)(2)(D) of the Social Security Act, 42 U.S.C. § 1395ww(d)(2)(D), with less than 50 beds as of December 27, 2020.

Eligibility Criteria

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

- The main licensed hospital of an OED 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.
- At the time the OED begins operating, the OED shall have a catchment area that is no less than 35 miles of travel distance established by roadways to a main licensed hospital or a campus that offers emergency services and is not under common legal ownership with the OED or another OED that is not under common legal ownership, **unless the OED is a CAH or small rural hospital transitioning to an OED.**
- The hospital shall continue to meet the statutory definition of "hospital" as defined in Section 802.1 of the Health Care Facilities Act by devoting 51% or more of its total beds to inpatient care.

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) Act⁶.

⁶ 40 P.S. § 1303.403.

- 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 independently⁷ 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).
 - 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

⁷ The OED cannot rely on services, rooms, equipment, staff, or supplies at the main licensed hospital to satisfy these requirements.

- 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 or 2022 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).