



STATE OF DELAWARE
STATE COUNCIL FOR PERSONS WITH DISABILITIES
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The Honorable John Carney
Governor

John McNeal
SCPD Director

MEMORANDUM

DATE: April 29, 2020

TO: Ms. Corrine Getchell, DHCQ
Office of Health Facilities Licensing and Certification

FROM: J. Todd Webb – Chairperson *JTW*
State Council for Persons with Disabilities

RE: 23 DE Reg. 817 [DHCQ Proposed Regulation Regarding Free Standing
Emergency Departments (April 1, 2020)]

The State Council for Persons with Disabilities (SCPD) has reviewed the Department of Health and Social Services' (DHSS) Division of Health Care Quality's (DHCQ's) proposed regulation which abrogates the existing one (4404) and re-numbers it 3340. The proposed regulation changes the name of the facility from Free Standing Emergency Center to Free Standing Emergency Department (FSED). DHSS originally published proposed regulations for FSED's in the July 1st, 2019 issue of the Delaware register of Regulations. The regulations are being republished as the Department made significant substantive changes to the previous proposed regulations. The proposed regulation was published as 23 DE Reg. 817 in the April 1, 2020 issue of the Register of Regulations. SCPD has the following observations and recommendations.

SCPD reviewed the July 2019 proposed regulation and, one of the criticisms of the regulation was that it did not specifically mention the Americans with Disabilities Act of 1990 (ADA) or Section 504 of the Rehabilitation Act of 1973 (Section 504). The ADA requires access to medical care services and the facilities where the services are provided. Private FSED's are covered by Title III of the ADA. Section 504 covers any FSED that received federal financial assistance (including Medicare and Medicaid reimbursements). SCPD stated that it would be better if the regulation specifically mentioned that the FSED must comply with the ADA and

Section 504 so that its application to persons with disabilities would be readily apparent (and not by inference).

Section 4.23 of the proposed regulation now requires FSED's to comply with the ADA and incorporates the act into the regulation. Likewise, section 4.24 requires FSED's to comply with Section 504 and incorporates the act into the regulation. SCPD appreciates and supports the revision.

Another criticism of the July 2019 regulation was that, although it mandated preparation of a written disaster preparedness plan for dealing with medical and non-medical emergencies, there was no specific language setting forth any requirements for dealing with patients with disabilities during an emergency. Section 15.2 of the proposed regulation now requires FSED's to "maintain a disability inclusive written disaster preparedness plan for natural and other disasters specific to the facility." SCPD appreciates and supports the revision.

A third criticism of the July 2019 regulation was that, although it required FSED's to comply with the rules and regulations of the Fire Prevention Commission and be inspected annually by the fire marshal, there was no specific language dealing with how patients with disabilities would be evacuated. Further, the regulation did not require that employees receive training in procedures to be followed for patients with disabilities. SCPD recommended that it would be better if the regulation had requirements that specified an evacuation route for patients with disabilities, including the width of any route and removal of any obstructions. Unfortunately, this issue was not addressed in the proposed regulation.

The proposed regulation adds a host of new definitions, including abuse, medication diversion, adverse incident, and emergency care. However, if a FSED is owned and operated by a hospital and is accredited by an organization approved by the Centers for Medicare and Medicaid Services, it is exempt from licensure and this regulation.

The regulation establishes a comprehensive licensing procedure, which includes an initial license (3.3.1), a provisional license (3.3.2), and an annual license (3.3.3). The regulation vests the Department of Health and Social Services with the authority to impose disciplinary action, including immediately suspending a license where there is an "immediate jeopardy or imminent danger to the public health, welfare and safety requiring emergency action." (3.5).

The regulation also sets up a comprehensive scheme of authority and responsibility. Every FSED must have a governing body that is responsible for the management, control, and operation of the facility. (5.0). There must be a director who is a full-time physician board certified in emergency medicine. He or she is responsible for the day to day operation and management of the FSED. (6.1.1; 6.1.2). The director is responsible for providing quality medical care. (6.1.3).

There must be a clinical director appointed by the director who is a registered nurse with substantial education, experience, and competence in emergency nursing. (6.2.1; 6.2.3.1). He or she must be a competent manager, administrator, and supervisor since the person provides general supervision and direction of the services offered by the FSED. (6.2.3.2; 6.2.3.3).

There are requirements for physicians (6.7) and nurses (6.8). There must be at least one (1) physician and one (1) registered nurse with training “in advanced cardiac life support and pediatric advanced life support in the FSED at all times.” (6.9).

The regulation requires FSED’s to have an infection prevention and control program based upon nationally recognized guidelines and standards such as the Centers for Disease Control and Prevention. (8.1).

The FSED must be properly built, equipped, and maintained to protect the health and safety of patients and employees. (10.1). A facility must have an adequate supply of linen that is processed in accordance with national standards for healthcare laundry. (10.2.1; 10.2.8). An FSED must have housekeeping services to ensure a clean, sanitary, and safe environment. (10.3.1). Waste must be properly stored and disposed of to prevent the transmission of disease (10.4.3), and the regulation adopts and incorporates, as requirements for FSED’s, the provisions of the Department of Natural Resources and Environmental Control Regulation Governing Solid Waste. (10.4.4).

FSED’s have to collect, maintain, and store patient medical records (while protecting confidentiality), and must be able to retrieve, authenticate, and distribute a patient’s medical records. Records can be kept in hard copy, electronically, or a combination of both. (11.0).

Drugs, controlled substances, and biologicals must be properly stored, accessible only to authorized employees, and prepared and dispensed “according to acceptable standards of practice.” (12.1; 12.4). FSED’s must comply with all state and federal laws, regulations and guidelines pertaining to pharmaceutical services (12.2), and must be registered under state and federal controlled substance acts. (12.3).

An FSED must provide a patient or patient’s representative with verbal and written notice of the patient’s rights (14.1) and also post the patient’s rights in the waiting room. (14.2). The notice must include the contact information of DHSS to which patients may report complaints. (14.2). The patient’s rights are broad and include treatment with respect and dignity; safety; privacy; care free from abuse, neglect, and exploitation; provision of appropriate information concerning the diagnosis, treatment and prognosis to the patient, patient’s designee, or legally authorized person; participation in decisions involving care and treatment except “when the patient’s participation is contradicted for medical reasons;” and the ability to complain about treatment and care that is or is not provided. (14.0 et. seq.) Information shall also be provided to patients and employees about patient conduct and responsibilities; services that the FSED provides; the fees and payment policies for the available services; and ways to express complaints and suggestions to the FSED. (14.4 et. seq.).

This regulation is a major effort to protect the state’s citizens and ensure they receive proper care from Free Standing Emergency Departments. The regulation is comprehensive and applies equally to all patients, including those with disabilities. The regulation specifically incorporates the ADA and Section 504. The regulation also requires a disability inclusive written disaster preparedness plan. That being said, SCPD still recommends that language be added to the fire

safety section to more adequately address the needs of individuals with disabilities. This is a laudable attempt by DHSS/DHCQ to ensure the quality of care and to regulate the provision of services patients receive from FSED's.

SCPD endorses the proposed regulation.

Thank you for your consideration and please contact the SCPD if you have any questions regarding our observations or recommendation on the proposed regulation.

cc: Ms. Yrene Waldon, DHCQ
Laura Waterland, Esq.
Governor's Advisory Council for Exceptional Citizens
Developmental Disability Council

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