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## Freestanding Emergency Departments: A Primer on Laws Impacting Development and Operation

By  
Anthony Del Rio\*

One of the latest types of facility being developed in the healthcare industry is the freestanding emergency department (“FSED”). In 2005, there were 146 FSEDs nation-wide. That number increased to 241 by 2009, representing 65% growth in the sector in just less than five years.<sup>1</sup> There are projected to be 400-500 FSEDs nation-wide today.<sup>2</sup> While FSEDs have existed in some states for dozens of years, over the past decade FSED development has blossomed and the facilities are growing in popularity as hospitals and healthcare systems strategize ways to reach new markets; provide improved, responsive care; and do so in the most cost-effective and efficient way. One of the primary drivers in the expansion of the FSED market has been overall demand for emergency services, and that demand is driven by multiple factors.

Overcrowded emergency departments and increasing demand for emergency services, which has nearly doubled in a decade, have been attributed to the closure of non-rural hospital emergency departments.<sup>3</sup> The increasing rate of failing hospitals has reduced access to emergency services, and the American College of Emergency Physicians assigned an overall grade of D- for access to emergency care in the 2014 National Report Card on America’s emergency care environment. Many previously suggested that increased emergency department use was due to uninsured utilizing emergency services because they

are unable to obtain primary care and hoped the Patient Protection and Affordable Care Act (the “ACA”) would stymie that demand; however, even after the passage and implementation of the ACA, emergency room visits continue to increase, with some of the busiest emergency rooms seeing increases of 20%-30%.<sup>4</sup> In addition to a growing demand for services, both consumers’ and payors’ expectations regarding quality and efficiency of services have increased. All of these factors are driving the feverish pace at which FSED development continues. However, because FSEDs, on a national level, are new to the healthcare market, there is wide gulf in both the public’s understanding of what FSEDs are and how governments regulate such entities.

The goal of this article is to serve as a primer on FSEDs. This article will: (I) explain what FSEDs are and how they differ from both urgent care centers and onsite hospital-based emergency rooms; (II) provide an overview of the two primary models of FSEDs; (III) discuss federal law considerations; and (IV) highlight various state-law considerations.

### **I. FSEDs and How They Differ from Other Facilities**

Unlike urgent care centers, which are typically open 12 to 14 hours a day, FSEDs are (in almost all cases) open 24-hours a day and 365 days a year. While typical urgent care patients present with low-to-moderate acuity (e.g., minor infections, flu symptoms, allergic reactions, minor lacerations, and sprains), FSEDs tend to treat moderate-to-high acuity patients (e.g., musculoskeletal injury, moderate lacerations, chest pain, asthma attacks).<sup>5</sup> To accommodate these higher-acuity

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<sup>1</sup> Michelle Andrews, *Emergency Care, But Not At A Hospital*, Kaiser Health News (May 31, 2011), <http://www.kaiserhealthnews.org/Features/Insuring-YourHealth/Michelle-Andrews-on-Hospital-ER-Alternatives.aspx> (last visited April 15, 2016).

<sup>2</sup> David Royse, *ERs Eye Lobbying to Win State Approval for Growth*, Modern Healthcare (July 4, 2015), <http://www.modernhealthcare.com/article/20150704/MAGAZINE/307049969>.

<sup>3</sup> Ning Tang, MD; John Stein, MD; Renee Y. Hsia, MD, MSc; Judith H. Maselli, MSPH; Ralph Gonzales, MD, MSPH, *Trends and Characteristics of US Emergency Department Visits, 1997-2007*, JAMA. 2010;304(6):664-670.

<sup>4</sup> Michael Sandler, *ER Visits Still Rising*, Modern Healthcare (Jan. 17, 2015).

<sup>5</sup> Alan A. Ayers, *Understanding the Freestanding Emergency Department Phenomenon*, The Journal of Urgent Care Medicine (Feb. 2014).

patients, while urgent cares are often supervised by family medicine or internal medicine certified physicians, FSEDs are generally overseen by emergency medicine certified physicians. Similarly, FSEDs are often staffed by nurses with emergency medicine training. In terms of lab services, urgent cares are usually limited to lab tests under a Clinical Laboratory Improvement Act (“CLIA”) waiver while FSEDs more often have CLIA certification and College of American Pathologist (“CAP”) or Commission on Office Laboratory Accreditation (“COLA”) accreditation.<sup>6</sup> Finally, regarding equipment, urgent cares generally have basic x-ray capabilities, while FSEDs often have CT and ultrasound.

Although FSEDs are capable of treating higher-acuity patients than urgent cares, they are generally less equipped than an onsite emergency department to handle patients suffering from serious trauma or showing symptoms that indicate they need services provided only in a hospital setting. Onsite emergency departments, particularly trauma centers, have greater access to resources, including inpatient beds and surgical services. If the patient’s injuries or symptoms indicate they will require surgery, an inpatient admission (particularly to intensive care), or percutaneous coronary intervention (“PCI”), then an onsite emergency department would likely be the more appropriate venue of care in order to avoid the necessity of ambulance transfer. Perhaps because of this, another notable difference between FSEDs and onsite emergency departments is that FSEDs more often than not do not receive patients via ambulance traffic.

In sum, FSEDs represent an intermediate level of care between an urgent care and a large emergency department located onsite at a major hospital. FSEDs are capable of treating higher-acuity patients than urgent cares and are generally able to treat patients more quickly than an onsite emergency department. However, while an FSED could be able to stabilize a patient that will ultimately need admission to a hospital, the more appropriate venue for such a patient would likely be an onsite emergency department.

<sup>6</sup> Anecdotally, HOPDs tend to favor CAP accreditation and IFECs are often COLA accredited.

## II. Two Primary FSED Models

The American College of Emergency Physicians (“ACEP”) recognizes two types of FSEDs: a hospital outpatient department (“HOPD”), also referred to as an off-site hospital-based or satellite emergency department, and independent freestanding emergency centers (“IFEC”).<sup>7</sup>

HOPDs are owned and operated by hospitals and are operated as outpatient departments of the owner-hospital, and, for that reason, are covered by the Provider Based regulations promulgated by the Centers for Medicare Services (“CMS”).<sup>8</sup> The next section discusses in greater detail the other Federal requirements applicable to this model, however, the Provider Based restrictions are important to note here because they effectively prevent hospitals from operating an HOPD as a joint venture. This is because, except for very limited exceptions, off-campus provider-based facilities must be wholly-owned by the hospital,<sup>9</sup> and because FSEDs are, by their nature, off-campus from a hospital, a joint venture would not be possible.<sup>10</sup> While a joint venture would not be possible, a hospital could potentially enter into a management contract with a third party; however, there are certain limitations on such agreements when utilized with Provider-Based facilities.<sup>11</sup> This is the only FSED model that CMS permits to be enrolled in Medicare, and some states, either explicitly by statute or through state agency action only permit this model of FSED to operate in their state.

IFECs, on the other hand, are typically owned by independent groups or individuals. The ownership structure of many IFECs is very similar to urgent cares, often being physicians or physician groups

<sup>7</sup> ACEP Policy Statement, *Freestanding Emergency Departments* (June 2014), <https://www.acep.org/clinical—practice-management/freestanding-emergency-departments/>

<sup>8</sup> 42 C.F.R. § 413.65.

<sup>9</sup> 42 C.F.R. § 413.65(e)(1)(i).

<sup>10</sup> If a hospital does not already have a full emergency department (e.g., a small specialty hospital), the hospital could potentially pursue a joint venture with another entity to open an emergency department within the same building of the specialty hospital or within 250 yards of the campus (which would qualify it as being on-campus under Provider Based rules).

<sup>11</sup> 42 C.F.R. § 413.65(h); see Catherine T. Dunlay and Thomas E. Dowdell, *Provider-Based Status, Under Arrangements, Enrollment and Related Medicare Requirements*, Health Lawyers, available at [https://www.healthlawyers.org/Events/Programs/Materials/Documents/MM12/papers/LL\\_dowdell\\_dunlay.pdf](https://www.healthlawyers.org/Events/Programs/Materials/Documents/MM12/papers/LL_dowdell_dunlay.pdf).

that have worked in emergency medicine for many years and pooled resources (or sought external funding) to open their own facility.

Because of how relatively new FSEDs are in the healthcare market, the market itself is predictably heavily fragmented. Although there are a handful of operators with dozens of FSEDs, a majority of the FSED operators in the country, whether HOPD or IFEC, each only own a few facilities.

### **III. Major Federal Laws Impacting FSEDs**

As an initial note, all of the major federal healthcare laws that affect other healthcare entities should be considered in the development and operation of a FSED, including the federal physician referral laws (“Stark”), Anti-Kickback Statute (“AKS”), and the privacy and security standards for health information implemented under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”). However, this section is focused on unique considerations related to FSEDs, specifically (1) Provider-Based rules, (2) Medicare Conditions of Participation (“CoPs”), and (3) the Emergency Medical Treatment and Labor Act (“EMTALA”).

As stated above, HOPDs are the only type of FSED that CMS recognizes.<sup>12</sup> This does not mean that federal laws do not permit opening IFECs, it simply means IFECs do not qualify for reimbursement from federal healthcare programs; however, on the same note, IFECs are not, under federal law, required to comply with the laws and regulations discussed in this section.

#### **1. Provider-Based Rules**

As a provider-based location of a hospital, the FSED must: (1) share common licensure with the hospital (if provided for under state law);<sup>13</sup> (2) be clinically integrated with the hospital<sup>14</sup> (e.g., same clinical oversight; report to the quality assurance, utilization review, and infection control committees; share a

unified record retrieval system; share the same medical staff and privileges); (3) be financially integrated with the hospital<sup>15</sup> (e.g., must be reflected on the hospital’s trial balance and be a cost center); (4) hold itself out to the public as a part of the hospital<sup>16</sup> (e.g., signage, forms, marketing); (5) have common ownership<sup>17</sup> (i.e., same legal entity and governing body as the hospital); (6) share the same administration and supervisions<sup>18</sup> (e.g., report to the CEO of the hospital, utilize the same administrative departments such as billing and payroll); and (7) be located within 35 miles of the hospital.<sup>19</sup> In addition, because HOPDs are emergency departments, they are required to comply with EMTALA (discussed below).<sup>20</sup>

#### **2. Medicare Conditions of Participation**

As a department of a Medicare-certified hospital, HOPDs must also meet the applicable CoPs.<sup>21</sup> Many of these CoPs are already directly or indirectly met if the HOPD is complying with Provider-Based rules, such as the medical staff of the HOPD being a part of the hospital’s medical staff,<sup>22</sup> the HOPD reporting to the hospital’s Governing Body,<sup>23</sup> the nursing staff complying with the hospital’s policies,<sup>24</sup> and the HOPD being a part of the hospital’s quality assessment and infection control programs.<sup>25</sup> In addition to these requirements, the CoPs also require that the HOPD have emergency laboratory services<sup>26</sup> and be able to meet the emergency needs of its patients in accordance with accepted standards of practice for hospital emergency departments.<sup>27</sup> The standards of practice requirement can afford surveyors a great deal

<sup>12</sup> CMS S&C Memo 08-08, 2008, *Requirements for Provider-based Off-campus Emergency Departments and Hospitals that Specialize in the Provision of Emergency Services* (January 11, 2008), available at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/downloads/SCletter08-08.pdf>.

<sup>13</sup> 42 C.F.R. § 413.65(d)(1).

<sup>14</sup> 42 C.F.R. § 413.65(d)(2).

<sup>15</sup> 42 C.F.R. § 413.65(d)(3).

<sup>16</sup> 42 C.F.R. § 413.65(d)(4).

<sup>17</sup> 42 C.F.R. § 413.65(e)(1)(i) and (ii).

<sup>18</sup> 42 C.F.R. § 413.65(e)(1)(iv).

<sup>19</sup> There are some unique exceptions to the 35-mile requirement, but they are very fact dependent and are rarely met. For a more in depth discussion of these unique exceptions, as well as Provider-Based requirements in general, see Elissa Moore and Bart Walker, *Hospitals and Health Systems: Provider-Based Status: The Rules and Common Issues*, 2008-4 *Bender’s Health Care Law Monthly* 1 (2008).

<sup>20</sup> 42 C.F.R. § 413.65(g).

<sup>21</sup> 42 C.F.R. § 482.1 through 482.45.

<sup>22</sup> 42 C.F.R. § 482.22.

<sup>23</sup> 42 C.F.R. § 482.12.

<sup>24</sup> 42 C.F.R. § 482.23.

<sup>25</sup> 42 C.F.R. § 482.21 and § 482.42.

<sup>26</sup> 42 C.F.R. § 482.27(b)(1).

<sup>27</sup> 42 C.F.R. § 482.55.



of leeway in evaluating an HOPD. Notably, the Medicare CoPs do not explicitly require an HOPD to be open 24-hours a day. However, the CoPs do require compliance with state law (which often requires 24-hour services) and the HOPD would still need to evidence how it is meeting the needs of patients if a patient were to present at the HOPD during the time at which the HOPD is closed.

While many of the requirements of the CoPs are the same or similar to Provider-Based requirements, practically speaking, demonstrating compliance with the CoPs can be more challenging. This is because Provider-Based rules provide for a voluntary attestation process and there is not a compulsory survey tied to the status. However, in order to evidence compliance with the CoPs, HOPDs will be surveyed during the hospital's Medicare recertification survey, and the addition of an HOPD to a hospital's certification can also potentially trigger an immediate survey of the new site, regardless of where the hospital is at in its certification cycle.<sup>28</sup> The HOPD survey will be performed in the same manner the primary hospital is surveyed, and the facility and staff should be prepared accordingly.

### 3. EMTALA

An HOPD is considered a "dedicated emergency department" under EMTALA.<sup>29</sup> This is a significant difference between HOPDs and IFECs. While many IFECs may, on a voluntary basis, accept any patient in need of emergency care, they are not legally required to do so (barring state-specific law). HOPDs are legally required under EMTALA to provide treatment to any patient in need of emergency care. This includes providing a medical screening examination and any necessary stabilizing treatment.<sup>30</sup>

<sup>28</sup> In my experience, although they can technically survey any time they choose, the Joint Commission ("JC") typically has adopted the position that if only a single HOPD is being added to a hospital's certification and the hospital already provides emergency services (thus, the HOPD is not an expansion in services, only location), JC will not immediately survey a new HOPD and will wait for the hospital's standard recertification survey. However, if multiple HOPDs are added to a hospital's certification, there is a much higher likelihood that it will trigger survey. I have personally only dealt with the JC when adding an HOPD to a hospital's Medicare certification. While JC is the largest Medicare surveyor, other contractors may have different practices.

<sup>29</sup> 42 C.F.R. § 489.24(b).

<sup>30</sup> 42 C.F.R. § 489.24(d).

## IV. State Law Considerations

Although the CoPs discussed above prescribe some basic requirements (but only for HOPDs), the bulk of the clinical and operational requirements placed on FSEDs typically originate from state law. This section does not focus on any one state, but rather discusses the primary considerations that should be analyzed in any state and provides examples of differing state laws.

### 1. Certificate of Need

While many states no longer have certificate of need ("CON") requirements, over half of states still maintain some form of CON requirement. Development of an FSED can generally trigger a CON in one of the three following ways: (1) if a CON is specifically required for the facility type;<sup>31</sup> (2) if a CON is required for expenditures that meet a certain threshold (generally ranges from \$1,500,000 – \$4,000,000) (e.g., North Carolina);<sup>32</sup> and (3) if a CON is required for certain services / equipment that FSEDs utilize, such as a CT scans (e.g., Rhode Island).<sup>33</sup>

### 2. Facility Licensing Requirements

Most states do not have a unique licensure category for FSEDs. Texas, ever the innovator, was one of the first states to pass laws and regulations specifically drafted for FSEDs, and Texas' regulations are almost certainly the most robust and well defined.<sup>34</sup> The regulations, as well as favorable laws regarding compensation for emergency care,<sup>35</sup> likely played a

<sup>31</sup> Most often this would be implicated by HOPDs that are either being developed with a new hospital or expanding services of the hospital in a way that would trigger CON requirements.

<sup>32</sup> N.C.G.S.A. § 131E-178.

<sup>33</sup> 23 R.I. Gen. Laws Ann. § 23-15-2 (10)(vi).

<sup>34</sup> The Texas Freestanding Emergency Medical Care Facility (FEC) Licensing Act (2009); 25 TAC 131.

<sup>35</sup> Although not discussed in this article, an external consideration in FSED development and operation is how state impacts reimbursement for emergency services (e.g., prudent layperson standard, balance billing). For a discussion on the development and impact of such laws, see Renee Y. Hsia, Jia Chan and Laurence C. Baker, *Do Mandates Requiring Insurers To Pay For Emergency Care Influence The Use Of The Emergency Department*, Health Affairs (July 2006), available at <http://content.healthaffairs.org/content/25/4/1086.full>.

large role in making Texas a leader in FSED development. Other states have a more middle-of-the-road approach and have amended regulations of outpatient facilities to include emergency services. For example, Colorado licenses FSEDs under their Community Clinic license as “Community Emergency Centers” and Arizona licenses FSEDs under the state’s Outpatient Treatment Center license.<sup>36</sup> Other state licensure laws restrict FSEDs to rural areas of the state (e.g., Nevada and Georgia).<sup>37</sup> Even still, other states only permit FSEDs to operate as satellite locations of a licensed hospital.<sup>38</sup>

In addition to the various licensure categories, one key difference that is not always directly addressed in licensure regulations is whether FSEDs are required to accept ambulance traffic. FGI Guidelines (defined below), which most states apply, do require FSEDs to have equipment that allows them to communicate with the ambulance network; however, that requirement does not necessarily translate into having to accept ambulance traffic. Although it may not be explicitly required by law, it may be a de facto requirement enforced by state agencies under the more general requirements around meeting the needs of patients. At the same time, ambulance networks often times maintain lists that prescribe to what facilities they should take certain patients, and such lists would likely exclude FSEDs for high acuity patients in need of surgical, trauma, or inpatient services.

### 3. Controlled Substances

Although the Drug Enforcement Agency (“DEA”) is the primary regulatory authority over controlled substances, state law plays a significant role in how FSEDs are able to acquire controlled substances. DEA license numbers (“DEA numbers”) are required in order to order controlled substances from suppliers; however, only certain types of individuals (e.g., physicians) or facilities (e.g., pharmacies, hospitals) licensed by states are permitted to obtain

DEA numbers. Because a majority of states have not enacted laws specifically regulating FSEDs, there are many states in which there is not a licensure vehicle through which an FSED is able to obtain a DEA number (absent establishing a pharmacy license for the facility). This results in precarious situations in which an FSED, in order to obtain controlled substances, must utilize the DEA number of a physician that is overseeing the facility, and many physicians are not comfortable with such arrangements. Even in Texas, the state that hosts as many FSEDs within its borders as exist in the rest of the country combined,<sup>39</sup> the Texas Association of Free-standing Emergency Centers (“TAFEC”) only recently persuaded the state legislature to add FSEDs to the definition of “hospital” under the state’s controlled substance act (which then permits FSEDs to seek a DEA number from the federal government).<sup>40</sup> Although lobbying state legislators to amend laws to address this gap is not a short-term solution to the issue, it is important to be aware of this unique challenge FSEDs face.

### 4. Building Codes and Structural Requirements

Building codes and architectural requirements are often assessed by regulators during facility development process, most commonly during state licensure or Medicare survey. State structural requirements vary across jurisdictions. Because FSEDs are, relatively speaking, a new building type, the codes and regulations related to FSED construction, as with licensure requirements, are not universal and can vary significantly by state. While the bulk of construction-related considerations are handled by the architects and the general contractors during the development process, it helps to have an understanding of the basic requirements. The two general guideposts that are almost universally applicable, particularly if the FSED will undergo a Life Safety survey by JC or another accreditation entity, are the International Building Code (“IBC”) and the

<sup>36</sup> 6 Colo. Code Regs. § 1011-1:IX.A-2; Ariz. Admin. Code R9-10-1019.

<sup>37</sup> Ga. Comp. R. & Regs. 111-8-40-.39.

<sup>38</sup> Although there is not specific rules directly on point for FSEDs, Florida permits hospitals to operate them: [http://ahca.myflorida.com/MCHQ/Health\\_Facility\\_Regulation/Hospital\\_Outpatient/Hospitals/EmergencyServices.shtml](http://ahca.myflorida.com/MCHQ/Health_Facility_Regulation/Hospital_Outpatient/Hospitals/EmergencyServices.shtml).

<sup>39</sup> The Texas Department of State Health Services reported over 200 licensed FSEDs as of December 2015. Directory available at <http://www.dshs.state.tx.us/facilities/find-a-licensee.aspx>.

<sup>40</sup> S.B. No. 1643, available at <http://www.legis.state.tx.us/tlodocs/83R/billtext/pdf/SB01643F.pdf#navpanes=0>; TAFEC press release available at <http://tafec.org/wp-content/uploads/2013-Leg-Update.pdf>.

National Fire Protection Association (“NFPA”).<sup>41</sup> The IBC categorizes FSEDs as business occupancy (so long as patients are at the facility less than 24 hours). This classification differs from hospitals, which are categorized as institutional, and thus subjected to additional structural requirements. IBC requirements are then supplemented by NFPA Life Safety requirements, which classifies FSEDs as ambulatory healthcare occupancy and requires additional smoke and fire protection measures that are not normally required in business occupancy buildings.

In addition to these basic codes, many states have adopted some version of the Facility Guidelines Institute (“FGI”) Guidelines for Design and Construction of Health Care Facilities (the “Guidelines”), and even those states that have not explicitly adopted the Guidelines rely on them in drafting their state code (e.g., Texas). The FGI updates the Guidelines every four years, and a majority of the states that have adopted the Guidelines have adopted the 2010 Edition. It is important to understand the Guidelines because in states that include architecture as a part of the healthcare facility licensure process (e.g., Arizona), interpretation and application of the Guidelines can become a point of contention. Unlike the IBC and NFPA codes, in addition to structural

requirements, the Guidelines prescribe specific services and equipment that an FSED should provide. In addition, the Guidelines prescribe two separate levels of emergency services that could potentially apply to FSEDs, and state regulators exercise a great deal of discretion in interpreting the FGI Guidelines and applying them to development projects. Because FSEDs are new to many regulators, being capable of both understanding what the Guidelines entail and being able to help educate regulators can be very important in the facility licensure process.

### **V. Conclusion**

FSEDs represent a new and, many argue, more efficient model of providing emergency services to a population with an ever growing demand for such services. Although some payors<sup>42</sup> and politicians<sup>43</sup> have balked at FSEDs, they are here to stay and will continue to expand. With the growth and maturation of the industry, regulations will continue to be developed and refined, but the considerations provided in this article should provide practitioners a good framework upon which to build.

<sup>41</sup> What version of the IBC and NFPA that a state applies to FSEDs (and healthcare facilities in general) can usually be found either in the state’s construction code or the state’s healthcare facility licensure code.

<sup>42</sup> [https://connect.bcbstx.com/in-the-community/b/weblog/archive/2015/12/07/beware-the-costs-of-free\\_2d00\\_standing-ers](https://connect.bcbstx.com/in-the-community/b/weblog/archive/2015/12/07/beware-the-costs-of-free_2d00_standing-ers).

<sup>43</sup> <http://www.bizjournals.com/denver/news/2014/02/27/battle-over-first-choice-emergency.html>; <http://www.providencejournal.com/article/20160322/NEWS/160329786>.