



The U.S. faces a significant need for robust primary care services. Demand is driven by an aging population and the increasing prevalence of chronic diseases. Traditional primary care providers are often unable to meet this escalating demand, leading to access challenges and strain on the broader healthcare system. As a result, freestanding emergency departments (FSEDs) are increasingly important in the healthcare delivery system. This two-part series examines the environment in which FSEDs operate and its valuation implications. In Part I,¹ we examined the competitive and reimbursement environments in which FSEDs operate. Part II delves into the regulatory environment shaping FSED operations, the technological innovations impacting their service delivery, and the overall industry outlook, ultimately exploring the implications for their valuation.

Regulatory Environment

Healthcare organizations face a range of federal and state legal and regulatory constraints, which affect their formation, operation, procedural coding and billing, and transactions. Some of the most pertinent regulations affecting FSEDs are discussed below.

Licensing and Accreditation

For FSEDs to be reimbursed by Medicare (as discussed in Part I), they must (1) maintain compliance with Medicare and state hospital emergency department (ED) requirements [e.g., hospital conditions of participation, EMTALA (discussed below)], (2) be integrated (both financially and clinically) with the parent hospital (i.e., they cannot be independent), (3) be advertised as affiliated with the parent hospital, and (4) be located within 35 miles of the affiliated hospital.² These requirements keep hospitals from launching FSEDs in rural areas or separate, additional service areas.³

Additionally, FSEDs may be regulated by a state's certificate of need (CON) law. A state CON program is one in which a government determines where, when, and how capital expenditures will be made for public healthcare facilities, services, and major equipment, and requires providers to demonstrate need for their services before establishing or expanding a healthcare facility or service.⁴ Currently, 35 states and Washington, D.C., have CON programs in place, although the exact requirements of each CON program vary widely; for example, only 28 state CON programs regulate hospitals.⁵

¹ Todd Zigrang and Jessica Bailey-Wheaton, "Valuation of Freestanding Emergency Departments (Part I of II)," The Value Examiner, May/June 2025, 26–31.

^{2 &}quot;Stand-Alone Emergency Departments," chap. 8 in *June 2017 Report to the Congress: Medicare and the Health Care Delivery System*, Medicare Payment Advisory Commission, June 2017, 248, https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun17_ch8.pdf.

³ Ibid., 250.

⁴ Adney Rakotoniaina and Johanna Butler, "50-State Scan of State Certificate-of-Need Programs," National Academy for State Health Policy, last updated December 12, 2024, https://nashp.org/state-tracker/50-state-scan-of-state-certificate-of-need-programs/.

⁵ Ibid

Fraud and Abuse Regulations

Fraud and abuse laws, specifically those related to the federal Anti-Kickback Statute (AKS) and physician selfreferral law (the "Stark Law"), may have the greatest impact on the operations of healthcare providers.

The AKS and Stark Law are generally concerned with the same issue: the financial motivation behind patient referrals. However, while the AKS is broadly applied to payments between providers or suppliers in the healthcare industry and relates to any item or service that may be paid for under any federal healthcare program, the Stark Law specifically addresses referrals from physicians, to entities with which the physician has a financial relationship, for the provision of defined services that are paid for by the Medicare program.⁶ Additionally, while violation of the Stark Law carries only civil penalties, violation of the AKS carries both criminal and civil penalties.7

Anti-Kickback Statute. The federal AKS makes it a felony for any person to "knowingly and willfully" solicit or receive, or to offer or pay, any "remuneration," directly or indirectly, in exchange for the referral of a patient for a healthcare service paid for by a federal healthcare program,8 even if only one purpose of the arrangement in question is to offer remuneration deemed illegal under the AKS.9 Notably, a person need not have actual knowledge of the AKS or specific intent to commit a violation of the AKS for the government to prove a kickback violation;¹⁰ the person only needs to have an awareness that the conduct in question is "generally unlawful." 11 Further, a violation of the AKS is sufficient to state a claim under the False Claims Act (FCA).12

Criminal violations of the AKS are punishable by up to 10 years in prison, criminal fines up to \$100,000, or both, and civil violations can result in administrative penalties, including exclusion from federal healthcare programs and civil monetary penalties plus treble damages (or three times the illegal remuneration).¹³ In addition to the civil monetary penalties paid under the AKS, if the AKS violation triggers liability under the FCA, defendants can incur additional civil monetary penalties of \$13,508 to \$27,018 per violation, plus treble damages.¹⁴

Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited.¹⁵ In response to these concerns, Congress has created a number of statutory exceptions and delegated authority to the U.S. Department of Health and Human Services (HHS) to protect certain business arrangements by means of promulgating several safe harbors. 16 These safe harbors set out regulatory criteria that, if met, shield an arrangement from regulatory liability and are meant to protect transactional arrangements unlikely to result in fraud or abuse.¹⁷ Failure to meet all of the requirements of a safe harbor does not necessarily render an arrangement illegal.¹⁸ It should be noted that, in order for a payment to meet the requirements of many AKS safe harbors, the compensation must not exceed the range of fair market value.

The HHS Office of Inspector General (OIG) made several revisions to the AKS in 2020, many of which are similar to revisions to the Stark Law made by the Centers for Medicare and Medicaid Services (CMS), as discussed below.19 Among the more notable revisions are new safe harbors for valuebased arrangements (wherein safe harbor requirements become less strict as participants take on more financial risk) and revisions to existing safe harbors.²⁰

- 8 Criminal Penalties for Acts Involving Federal Health Care Programs, 42 U.S.C. § 1320a-7b(b)(1).
- 9 "Re: OlG Advisory Opinion No. 15-10," letter from Gregory E. Demske, Chief Counsel to the Inspector General, to [Name Redacted] (July 28, 2015), 4-5, https://oig.hhs.gov/fraud/docs/ advisoryopinions/2015/AdvOpn15-10.pdf; U.S. v. Greber, 760 F.2d 68, 69 (3d Cir. 1985).
- 10 Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §§ 6402, 10606, 124 Stat. 119, 759, 1008 (March 23, 2010).
- 11 Jennifer A. Staman, "Health Care Fraud and Abuse Laws Affecting Medicare and Medicaid: An Overview," Congressional Research Service, September 8, 2014, 5, https://www.fas.org/sgp/crs/ misc/RS22743.pdf.
- 12 "Health Care Reform: Substantial Fraud and Abuse and Program Integrity Measures Enacted" (newsletter, McDermott Will & Emery, April 12, 2010), 3; Patient Protection and Affordable Care Act.
- 13 Criminal Penalties for Acts Involving Federal Health Care Programs, 42 U.S.C. § 1320a-7b(b)(1); Civil Monetary Penalties, 42 U.S.C § 1320a-7a(a).
- 14 False Claims, 31 U.S.C. § 3729(a)(1)(G); Civil Monetary Penalties Inflation Adjustments for 2023, 88 Fed. Reg. 5776, 5777 (January 30, 2023).
- 15 "Re: OIG Advisory Opinion No. 15-10," 5.
- 16 Ibid.
- 17 Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute: Final Rule, 64 Fed, Reg, 63518, 63520 (November 19, 1999).
- 18 "Re: Malpractice Insurance Assistance," letter from Lewis Morris, Chief Counsel to the Inspector General, U.S. Department of Health & Human Services, to [Name redacted] (January 15, 2003), https://oig.hhs.gov/fraud/docs/alertsandbulletins/malpracticeprogram.pdf.
- 19 Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 85 Fed. Reg. 77684, 77814-77815 (December 2, 2020).

^{6 &}quot;Comparison of the Anti-Kickback Statute and Stark Law," Health Care Fraud Prevention and Enforcement Action Team (HEAT), Office of Inspector General (OIG), U.S. Department of Health & Human Services, accessed July 6, 2025, https://oig.hhs.gov/documents/provider-compliance-training/939/StarkandAKSChartHandout508.pdf.

The Stark Law prohibits physicians from referring Medicare patients—for the provision of designated health services—to entities with which the physicians or their family members have a financial relationship.

Stark Law. The Stark Law prohibits physicians from referring Medicare patients—for the provision of designated health services (DHS)—to entities with which the physicians or their family members have a financial relationship.²¹ Further, when a prohibited referral occurs, entities may not bill for services resulting from the prohibited referral.²² Under the Stark Law, DHS include inpatient and outpatient hospital services.²³

Under the Stark Law, financial relationships include ownership interests—through equity, debt, or other means—in entities that provide DHS. They also include indirect ownership; that is, ownership interests in entities that have ownership interests in DHS providers.²⁴ Additionally, financial relationships include compensation arrangements, which are defined as arrangements between physicians and entities involving any remuneration, directly or indirectly, in cash or in kind.²⁵

Civil penalties under the Stark Law include overpayment or refund obligations, potential civil monetary penalties of \$15,000 for each service, plus treble damages, and exclusion from the Medicare and Medicaid programs.²⁶ Further, similar to the AKS, violation of the Stark Law can trigger a violation of the FCA.²⁷

Notably, the Stark Law contains a large number of exceptions that describe ownership interests, compensation arrangements, and forms of remuneration to which the law does not apply.²⁸ Similar to the AKS safe harbors, without these exceptions, the Stark Law might prohibit legitimate business arrangements. Note that to meet the requirements of many

exceptions related to compensation between physicians and other entities, compensation must (1) not exceed the range of fair market value, (2) not take into account the volume or value of referrals generated by the compensated physician, and (3) be commercially reasonable. Unlike the AKS safe harbors, an arrangement must fully fall within one of the exceptions to be shielded from enforcement of the Stark Law.²⁹

As noted above, CMS made several revisions to the Stark Law in December 2020. These include:

- Revised definitions of fair market value, general market value, and commercial reasonableness; and
- New permanent exceptions for value-based arrangements.³⁰

The new value-based arrangements exceptions protect the following arrangements:

- Full financial risk arrangements. These include capitated payments and predetermined rates or a global budget.
- Value-based arrangements with meaningful downside financial risk. In these arrangements, physicians pay no less than 25 percent of the value of the remuneration they receive when they do not meet predetermined benchmarks.
- Value-based arrangements. The exception applies regardless
 of risk level to encourage physicians to enter value-based
 arrangements, even if they only assume upside risk.³¹

²¹ Jennifer O'Sullivan, "CRS Report for Congress: Medicare: Physician Self-Referral ('Stark I and II')," Congressional Research Service, July 27, 2004, available at http://www.policyarchive.org/handle/10207/bitstreams/2137.pdf; Limitation on Certain Physician Referrals, 42 U.S.C. § 1395nn.

²² Limitation on Certain Physician Referrals, 42 U.S.C. § 1395nn(a)(1)(A).

²³ Ibid., § 1395nn(a)(1)(B); "Definitions," 42 CFR § 411.351 (2015). Note the distinction in 42 CFR § 411.351 regarding what services are included as DHS: "Except as otherwise noted in this subpart, the term 'designated health services' or DHS means only DHS payable, in whole or in part, by Medicare. DHS do not include services that are reimbursed by Medicare as part of a composite rate [for example, SNF Part A payments or ASC services identified at § 416.164(a)], except to the extent that services listed in paragraphs (1)(i) through (1)(x) of this definition are themselves payable through a composite rate (for example, all services provided as home health services or inpatient and outpatient hospital services are DHS)."

²⁴ Limitation on Certain Physician Referrals, 42 U.S.C. § 1395nn(a)(2).

²⁵ Ibid., § 1395nn(h)(1).

²⁶ Ibid., § 1395nn(g).

^{27 &}quot;Comparison of the Anti-Kickback Statute and Stark Law."

²⁸ Limitation on Certain Physician Referrals, 42 U.S.C. § 1395nn.

^{29 &}quot;Comparison of the Anti-Kickback Statute and Stark Law."

³⁰ Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 85 Fed. Reg. 77492 (December 2, 2020).

³¹ Ibid., 77510-77528.

Note: Regulatory scrutiny of healthcare entities (especially with regard to fraud and abuse violations) has generally increased over the past decade. Therefore, under current regulations, the severe penalties that may be levied against healthcare providers under the AKS, the Stark Law, or the FCA will likely raise a hypothetical employer's estimate of the risk related to the value of FSED services.

Emergency Medical Treatment and Labor Act (EMTALA)

EMTALA requires Medicare-participating hospitals that operate EDs (such as FSEDs) to provide "an appropriate medical screening examination" to any patient that presents to the ED.³² Further, if the hospital determines that a patient is in active labor or is suffering from some other emergency condition, the hospital is required to provide treatment for the patient regardless of the patient's insurance status or ability to pay.33 If the hospital (or FSED) cannot provide appropriate treatment, or if the patient requests, the hospital must transfer the patient to a more suitable site.³⁴ Medicare-participating hospitals that fail to comply with EMTALA regulations may (1) lose their status as a Medicareparticipating hospital, (2) incur civil monetary penalties of up to \$50,000, and/or (3) be liable for damages in civil actions brought by patients or other medical facilities that were harmed as a result of the violation of EMTALA.35

Technological Environment

In recent years, there has been a rapid adoption of technological innovations in the U.S., which has fundamentally changed the healthcare delivery system.³⁶ Research indicates that implementation of healthcare information technology (HIT)—which includes a variety of software applications (e.g., billing software), staffing models, and electronic health records (EHR)—may lead to improved efficiency and quality management.37 EHR systems in particular are linked to clinical improvements³⁸ and have the ability to reduce costs, enhance quality and coordination of care, and increase efficiencies.39 The adoption of EHR systems has deepened communication along the continuum of care by connecting outpatient providers directly with patients, primary care physicians, and hospitals. 40 Increased utilization of EHR systems also has the potential to:

- Improve access to information for patients, insurance companies, and billing departments;
- Expedite access to scans, diagnostic testing results, surgery information, medication history, allergy information, and patient medical history;
- Speed up medical record documentation and generation of discharge instructions and patient education materials;
- Reduce information and documentation errors; and
- Accelerate data gathering for quality assurance, research, analytic comparisons, and other benchmarking purposes.41

In addition to HIT and EHR, telehealth services can streamline healthcare delivery by supplementing or replacing face-to-face encounters with physicians. The technology shows great potential for meeting the growing demand for medical services and the shortage of physicians. Moreover, telehealth services can be more cost-efficient for the patient and the provider than face-to-face encounters.⁴² For FSEDs in particular, providers can use telehealth for consultations with specialists (e.g., neurologists, cardiologists) in real-time, potentially avoiding unnecessary transfers.

- 33 Ibid.
- 34 "Emergency Medical Treatment & Labor Act (EMTALA)"; Examination and Treatment for Emergency Medical Conditions and Women in Labor, 42 U.S.C. § 1395dd(b).
- 35 Examination and Treatment for Emergency Medical Conditions and Women in Labor, 42 U.S.C. § 1395dd(d).
- 36 "The Impact of Technology in Healthcare," American Institute of Medical Sciences and Education, Healthcare Training Blog, June 2, 2019, https://www.aimseducation.edu/blog/the-impact-oftechnology-on-healthcare/.
- 37 Andrew Kramer, MD, et al., "Understanding the Costs and Benefits of Health Information Technology in Nursing Homes and Home Health Agencies: Case Study Findings," U.S. Department of Health and Human Services, Assistant Secretary for Planning and Evaluation, Office of Disability, Aging and Long-Term Care Policy, June 2009, iv-v, 1, https://aspe.hhs.gov/sites/default/files/ migrated legacy files//43226/HITcsf.pdf.
- 38 "Improved Diagnostics and Patient Outcomes," U.S. Department of Health and Human Services, Assistant Secretary for Technology Policy, accessed July 6, 2025, https://www.healthit.gov/ topic/health-it-and-health-information-exchange-basics/improved-diagnostics-patient-outcomes.
- 39 "The Impact of Technology in Healthcare"; "Medical Practice Efficiencies and Cost Savings," U.S. Department of Health and Human Services, Assistant Secretary for Technology Policy, accessed July 6, 2025, https://www.healthit.gov/topic/health-it-and-health-information-exchange-basics/medical-practice-efficiencies-cost-savings#:~:text=Many%20health%20care%20 providers%20have,Reduced%20transcription%20costs.
- 40 Laurel Stoimenoff and Nate Newman, "Urgent Care Industry White Paper: The Essential Role of the Urgent Care Center in Population Health" (Urgent Care Association, November 2019), 17.
- 41 Lisa Waters-Davis, "A Special Report on the State of Electronic Medical Records Implementation in Outpatient Surgery," Outpatient Surgery Magazine, February 11, 2013, https://www.aorn.org/ outpatient-surgery/article/2013-February-got-emr.
- 42 Jack Curran, "IBISWorld Industry Report OD5775: Telehealth Services in the US," IBISWorld, October 2019, 4.

³² Consolidated Omnibus Budget Reconciliation Act of 1985, Pub. L. No. 99-272, § 9121, 100 Stat. 82, 164 (April 7, 1986); "Emergency Medical Treatment & Labor Act (EMTALA)," Centers for Medicare and Medicaid Services, last modified December 6, 2024, https://www.cms.gov/Regulations-and-Guidance/Legislation/EMTALA/; Examination and Treatment for Emergency Medical Conditions and Women in Labor, 42 U.S.C. § 1395dd(a).



Industry Outlook and Valuation Implications

The U.S. FSED market size was estimated at \$16.55 billion in 2024 and is projected to grow at an annual rate of 5.9 percent from 2025 to 2030.⁴³ Merger and acquisition activity in the FSED sector has been composed mostly of hospital/health systems acquiring independent operators or buy-in/buy-out of shareholders in independent facilities.

The FSED transactional marketplace has been driven by the following factors:

- Evolving consumer preferences. Patients increasingly demand convenience, nearby location, reduced wait times, and enhanced accessibility to state-of-the-art facilities.
- Growing incidence of chronic diseases and aging population. These factors increase demand for convenient healthcare services offered by FSEDs.
- On-site diagnostic services. On-site, state-of-the-art diagnostic capabilities, similar to what is found in a hospital-based ER (e.g., imaging and lab tests) has increased reliance on these facilities as one-stop care delivery sites.

- Cost effectiveness. FSEDs operate at lower costs than hospital-based emergency rooms, making them attractive for both patients and payors seeking alternatives to traditional hospital-based ERs.
- Telehealth services. Telehealth in FSEDs allows for remote initial patient assessment and screening, speeding up the determination of the appropriate level and location of care and increasing access to specialists.
- Strategic collaborations and partnerships.
 Partnerships between FSEDs, hospitals, and other care delivery sites (such as retail or walk-in clinics) improve patient flow, reduce ER congestion, and expand service offerings.

An FSED's ability to take advantage of the above factors has a positive impact on its value. Additional factors that impact the value of FSEDs include:

 Revenue size and growth rate. Facilities with larger revenue bases and strong growth trends may indicate a higher value due to their stability and scalability.

^{43 &}quot;U.S. Freestanding Emergency Department Market Size, Share & Trends Analysis Report by Ownership (OCED, IFSED), by Services (ED Services, Laboratory Services, Imaging Services), and Segment Forecasts, 2025–2030," Grand View Research, accessed April 23, 2025, https://www.grandviewresearch.com/industry-analysis/us-freestanding-emergency-department-market.

- Payor mix and contracting. Facilities with favorable payor contracts and a diversified payor mix tend to be more attractive to buyers, which may command a higher value.
- Operational efficiency. Efficient staffing models—e.g., using advanced practice providers (APPs) where appropriate—and low employee turnover can improve margins and enhance value. FSEDs' average net profit margin is approximately 23 percent, and the average adjusted earnings before interest, taxes, depreciation, and amortization (EBITDA) margin is approximately 31.25 percent of revenue.
- Market demographics. Facilities located in areas with favorable demographics and limited competition may command premium valuations due to growth potential.
- Service diversification. Offering additional services such as occupational medicine, telehealth, or diagnostic imaging—can diversify revenue streams and increase a center's attractiveness to buyers.
- Quality of care. Facilities may be accredited by organizations, such as The Joint Commission, the American College of Emergency Physicians (ACEP), or other specialty organizations (e.g., the American College of Cardiology). These accreditations can enhance the perception of quality with the community and payors.

Market multiples refer to the estimated purchase price, or enterprise value, related to adjusted EBITDA. The typical range of market multiples for FSEDs is three to six times adjusted EBITDA, depending, in part, on the facility's performance with respect to the above factors.

Conclusion

Demand for services offered by FSEDs is closely tied to the greater U.S. healthcare industry, which is rapidly evolving. For example, providers have financial incentives to treat patients in the ED because Medicare's total ED payment (facility payment plus physician payment) is higher than its total payment made in other settings for comparable cases. However, site-neutral payment policies (which would equalize payments across various outpatient providers) are coming back into favor with congressional leaders eager to cut government spending. This may render currently favorable reimbursement rates uncertain for FSEDs going forward, and any change in reimbursement—such as changing the FSED payment system from HOPD rates to ambulatory surgery center (ASC) rates—would significantly reduce FSED revenues from Medicare.⁴⁴

Additionally, increased scrutiny faced by healthcare providers under the AKS and the Stark Law, as well as the severe penalties that may be levied against healthcare providers for violations of those laws, may increase risk, tempering the value of these enterprises. At the same time, the number of healthcare services provided at FSEDs continues to increase due to technological advances that allow many services and procedures to be performed in a safe, high-quality, and often less costly environment than at many hospital-based EDs and physician offices. Overall, FSEDs are well positioned to continue to be a major player in the future model of healthcare delivery as these initiatives continue to develop.



Todd A. Zigrang, MBA, MHA, FACHE, CVA, ASA, ABV, is president of Health Capital Consultants, where he focuses on the areas of valuation and financial analysis for hospitals and other healthcare enterprises. Mr. Zigrang has significant physician integration and financial analysis experience, and has participated in the development of a physician-owned, multispecialty management service organization and networks involving a wide range of specialties, physician-owned hospitals, as well as several limited liability companies for acquiring acute care and specialty hospitals, ASCs, and other ancillary facilities. Email: tzigrang@healthcapital.com.



Jessica L. Bailey-Wheaton, Esq., serves as senior vice president and general counsel of Health Capital Consultants. Her work focuses on the areas of Certificate of Need (CON) preparation and consulting, as well as project management and consulting services related to the impact of both federal and state regulations on healthcare transactions. In that role, Ms. Bailey-Wheaton provides research services necessary to support certified opinions of value related to the fair market value and commercial reasonableness of transactions related to healthcare enterprises, assets, and services. Email: jbailey@healthcapital.com.

⁴⁴ See, e.g., "CY 2020 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule (CMS-1717-FC)," Centers for Medicare and Medicaid Services, November 1, 2019, https://www.cms.gov/newsroom/fact-sheets/cy-2020-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-0.