



Health-chising: *Starting-up a Health Care Franchise*

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Health-chising: Starting-up a Health Care Franchise

In recent years, health care franchises have grown at a rapid pace.[1] Yet, it is worth noting that franchising is not a new concept to the health care industry. Health care franchise systems have been around for decades and these systems continue to grow and evolve to distribute many health care-related products and services to consumers. Given the growth and success of health care franchises, some entrepreneurs are taking a closer look at franchising their health care-related businesses.[2] Of course, franchising is not for every health care business concept, but for those concepts that are considering it, we have identified five Q&As that could impact the decision:

What is franchising exactly?

Franchising typically occurs when the franchise concept owner (i.e., franchisor) for a fee grants an independent business operator (i.e., franchisee) the right to use the franchisor's business system and trademark to distribute goods or services to consumers. Franchising is a highly regulated arrangement, and the legal provisions governing the arrangement vary widely from federal to state law and between states.

What are some key franchise regulations to be aware of?

Like the health care industry, franchising arrangements include broad and complex regulations that entrepreneurs will have to navigate to operate in a compliant manner. If you decide to franchise your health care business, you should be familiar with franchise disclosure, registration, and relationship laws.

In the United States, franchising is regulated at both the federal and state level. Whether under federal or state law, a franchisor is required to provide a franchise prospect with a franchise disclosure document (“FDD”). At a minimum, the FDD includes the franchise agreement for the franchise offering along with 23 items of legally-mandated disclosures that address the operational, financial, and legal aspects of the franchise offering and the franchise system. In addition to franchise disclosure requirements, certain states (such as California, Illinois, and New York) require franchisors to register their FDDs for state review and approval before they may offer or sell their franchises to franchise prospects.

Finally, in the United States, there are a number of states that have laws that govern the ongoing relationship between the franchisor and franchisee. The scope of these laws varies considerably, and the laws provide additional legal protections to franchisees on issues relating to a franchisor’s decisions on franchise terminations, renewals, and transfers.

What types of health care businesses have been franchised?

Many different health care concepts have been franchised, including home health care, senior assisted living, optometry services, medical equipment, diagnostics and therapeutic services, and urgent care services. Franchise systems in the health care industry range in size from a few franchise units to over a thousand franchise units, and some health care franchise systems have operated for many decades.

How do we incorporate our health care legal requirements and business practices into a franchise program?

The specific health regulations and practices that must be disclosed in the FDD will depend on the type of health care services that you will provide. Some of the more common regulatory issues that intersect both franchising and health care include: ownership structure of the franchisor and prospective franchisee (e.g., physician/nonphysician ownership) and practices and procedures with respect to information security, referrals, reimbursement, and fee-splitting.

- A. Anti-Kickback: The federal Anti-Kickback Statute^[3] (“AKS”) prohibits health care providers from providing or receiving anything of value in exchange for referrals paid for by federal programs (e.g., Medicare or Tricare). Professional service rebates, excessive fees for support services, or any other item of value can form the basis for a government AKS claim. Several states have adopted anti-kickback statutes of their own. Fortunately, the federal statute and most state statutes include “safe harbor” provisions that allow certain legitimate contracts and payments that would otherwise be prohibited. Ensuring your health care franchise agreements meet all requirements to qualify for safe harbor protection is essential to running a compliant franchise system.

- B. Corporate Practice of Medicine: Most states prohibit the corporate practice of medicine (or “CPOM”) to ensure licensed health care professionals are exercising independent judgment in providing treatments to patients. Typically, CPOM statutes or regulations prohibit a nonphysician from owning or controlling physician practice or even sharing in the fees generated from professional services. In some states, violations carry severe penalties including jail time and significant fines.^[4] When structuring a franchise system, the franchisor must ensure that licensed health care professionals will maintain their independent medical judgment.

- C. HIPAA and Data Protection: The Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and state data protection requirements for the protection of individually identifiable patient information can complicate the health care franchise. Franchisees typically benefit from receiving detailed analyses of the franchisor’s compiled data to assist scheduling employees, ordering supplies, and managing profitability. HIPAA and state data protection laws may require additional safeguards or specialized arrangements to ensure patient data is used appropriately. Structuring a franchise agreement to incorporate the relevant data protection laws from the start will help mitigate risk while allowing the benefits a franchise system has to offer.
- D. Stark Law and Self-Referral: The Stark Law is a federal prohibition on physicians referring patients to certain designated health service providers (e.g., hospitals, clinical labs, imaging, and outpatient prescription drugs) that will be paid by Medicare with whom they have a financial relationship, unless a regulatory exception applies.^[5] Several states have adopted similar self-referral prohibitions. The state laws vary widely as to which types of health care professionals are covered, which federal payers are covered, the types of medical services referred, and whether family members are included. Stark and state self-referral laws may be implicated if the franchise system’s licensed professionals will refer to a related lab or pharmacy.

What steps should I take if I want to franchise my health care concept?

Although franchising (especially in the health care industry) is highly regulated and complex, the distribution model has proven successful in

many contexts if properly structured. As you would expect, you will need competent legal and business counsel to walk you through the complex analysis of establishing a health care franchise. Below, please find five general steps that you should take when considering franchising your health care business:

1. Prove your health care business model works by showing that your current operations have been successful.
2. Document your business' system — i.e., its operation, standards, procedures, and practices — in such a manner that the system may be replicated by others.
3. Analyze and determine the financial and operational demographic profile of your franchisee prospects.
4. Create a legally compliant financial model for the franchise system that accounts for franchisor's and the franchisee's expected rate of return.
5. Decide which franchisor-related tasks (e.g., marketing, sales, training, etc.) will be handled internally and which will be outsourced.

[1] See (a) Beth Ewen, *Healthcare Tops All Others in FT's Top 200+ Ranking*, FRANCHISE TIMES, (September 2016), <http://www.franchisetimes.com/news/September-2016/Healthcare-Tops-All-Ot...>, (b) Jeffrey McKinney, *Rush is on for healthcare providers* FRANCHISE TIMES, (Aug. 2015), <http://www.franchisetimes.com/August-2015/Rush-is-on-for-healthcare-prov...>, and (c) Jason Dav, *Why Health-Care Franchising Is Entering a Boom Time*, ENTREPRENEUR MAGAZINE, (March 2014), <https://www.entrepreneur.com/article/231788>.

[2] Although outside the scope of this Alert, franchising in the healthcare industry has expanded both before and after the Affordable Care Act ("ACA"). Given the recent elections and current discussion surrounding the ACA, we will continue to monitor and analyze President-elect Trump's and Congress' plans regarding the ACA and such plans' potential effect on certain aspects of the healthcare franchise model.

[3] 42 U.S.C. § 1320a-7b.

[4] See N.Y. Educ. Law § 6512

[5] 42 U.S.C. § 1395nn.

