



FRANCHISING IN THE HEALTH CARE INDUSTRY

GRAY, PLANT, MOOTY, MOOTY & BENNETT, P.A.
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LEGAL COMPLEXITIES OF FRANCHISING IN THE HEALTH CARE INDUSTRY

A paper presented by

**John Gilliland
The Gilliland Law Firm, P.C.
Indianapolis, Indiana**

**Mark A. Kirsch
Gray, Plant, Mooty, Mooty & Bennett, P.A.
Washington D.C.**

**Mark Siebert
The iFranchise Group
Homewood, Illinois**

at the

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LEGAL COMPLEXITIES OF FRANCHISING IN THE HEALTH CARE INDUSTRY ^{*}

I. INTRODUCTION

When most people think of franchising they think of the traditional commercial or business format franchises, such as a fast-food chain (McDonald's or Subway), a hotel chain (Comfort Inn), an automobile service (Jiffy Lube), or a home maintenance business (Roto Rooter). Hardly does it cross the mind of the average American consumer that professional services – including health care services – are franchised, nor that some of those professional services have been franchised for over 50 years.

The term “health care,” as well as references to health care services and health care businesses, include a wide variety of businesses and services. Many health care franchises may fall into traditional health care services or practices provided by a licensed physician or other professional, such as dental clinics, urgent care centers, and chiropractic clinics. Other franchises provide health-related services, such as senior care, or health-related products, such as hearing aids. There are other businesses that are only tangentially related to health care, or may sell products or services that promote health or a healthful appearance, such as companies offering weight loss programs, nutrition products, medical supplies, and even tanning businesses. This paper focuses primarily on the health care and health-related services in the first two broad categories.¹ However, the franchise practitioner should be aware that while health laws and regulations affect these traditionally recognized health care businesses, they may also be applicable to aspects of some of these ancillary health care businesses.

This paper explores the growth of franchising in the health care professions, with particular emphasis on the business, legal and regulatory challenges associated with developing a health care franchise system and operating a health care franchised business. The paper will address how the federal and state health laws and regulations shape and influence a franchise system, contractual arrangements and operating obligations. Franchise practitioners advising health care or health-related franchises need to understand that the legal, statutory, regulatory and licensure restrictions and requirements may be different for, or have different effects, depending on the health care profession or business that is being franchised. These limitations include restrictions on the ownership of the franchised business; the types of services offered; the collection, use and protection of data; the patients or customers² to whom the franchisees may offer their products or services; and/or the fees paid by the franchisee to the franchisor.

*Mark Kirsch would like to thank two of his partners at Gray Plant Mooty for their valuable assistance in the preparation of this paper: Danell Caron in the franchise group, and Jesse Berg in the health care group.

¹For certain aspects of this paper, and for some of the analysis of data described in Section I below, the authors utilized the categories and definitions of health care services found in the July 2014 *Entrepreneur Magazine* Franchise 500. In that guide, there are 2,211 franchise companies listed, 41 of which could be broadly categorized as “health services.” A list of health care-related businesses, along with a brief description of the business, from *Entrepreneur Magazine* is included in Appendix A. In addition, Appendix A includes a description of franchised health care businesses that FRANdata, a leading franchise research company, has utilized in connection with some of its research. While health laws may have specific applications to certain practices or businesses, the public perception, and the business analysis, will often view health care businesses more broadly.

²The authors utilize the terms “patients,” “clients” and “customers” interchangeably in this paper. While some customers of a health care business, such as an urgent care facility, are generally referred to as patients, the purchaser of a hearing aid device at an audiologist, may be considered a customer, and not a patient.

Section I of this paper examines the development of franchise companies in the health care sector over the past ten years, as well as the lessons learned and the factors that need to be addressed in order to create a profitable and legally compliant health care franchise system. Section II of this paper includes a high level overview of health laws and regulations which practitioners advising health care or health-related franchises should understand, with a focus on those laws that tend to have the most significant effect on health care franchises. Section III provides a detailed analysis of the impact of these laws on franchising, and how franchise systems, including franchisors and franchisees, must operate to maintain compliance with a wide variety of regulatory obligations. For example, some of these laws and regulations may force a significant restructuring of the franchise system and the franchisor-franchisee relationship (due to the prohibitions of the corporate practice of medicine doctrine); some may alter the operational obligations of each health care business (such as licensures and certifications, and fraud and abuse laws), and some may impact both the internal and external operations and communications of both the franchisor and franchisee (such as information gathering and privacy protection under HIPAA). Section III also addresses agreements and contractual provisions that are required, or recommended, to maintain compliance with the health laws. Section III concludes with a discussion of certain franchise disclosure obligations (including FDD drafting tips and state franchise registration issues) applicable to offering health care franchises.

A. A Brief History of Franchising in the Health Care Professions

1. The First Wave: Product-Based Systems

The franchise business model was slow to be adopted by entrepreneurs in health care professions. For example, Kenneth Dahlberg founded Miracle-Ear in 1948, upon returning from World War II and being unable to find a suitable hearing aid. But Dahlberg did not begin to franchise the concept until 1983. Likewise, Pearle Vision was founded in 1961, but did not begin franchising until 1980. One example of an early use of the franchise business model in a non-medical, but “professional” business is Henry and Richard Bloch, who founded H&R Block in 1955 as an accounting and tax preparation service and began franchising in 1956. One other entrepreneur who is an example of an early adopter of the franchise business model for a regulated profession was Joel Hyatt who founded Hyatt Legal services in 1977 and began franchising that same year.

Perhaps the earliest adopter of the franchise model in a health care-related business was Louis Kohl Liggett who organized the Drug Merchants of America in 1901 with 40 original franchisees, eventually naming it Rexall. At its height in 1958, Rexall had more than 11,100 stores, twenty percent of the national pharmacy market. That is more than double the size of the current pharmacy chain leader, CVS.

Although Miracle-Ear, Pearle Vision, Hyatt Legal and franchised pharmacies like Medicine Shoppe (currently owned by Cardinal Health) and HealthMart all compete in vastly different markets, one common trait with many other franchisors during this time was a focus on “product” sales, which is more commonly called “product distribution” franchising. Pearle Vision provides a relevant example. Each store had an ophthalmologist who would conduct eye exams, vision tests, and prescribe glasses. However, Pearle Vision was prevented from collecting a royalty, because of the corporate practice of medicine doctrine and other health laws and regulations (discussed below in Sections II and III), which prohibited a business entity not owned by the physician from practicing medicine or employing a physician to provide professional medical services. To overcome the restriction posed by this requirement, Pearle Vision instead focused its business model on the sale of glasses and accessories.

Today, that model of product distribution is followed by companies such as McKesson, owner of HealthMart. Instead of charging a traditional monthly royalty based on sales, it charges a flat monthly fee. Also, instead of the traditional twenty-year contract in which the franchisee does not have a right to cancel and leave the franchise, McKesson uses a 10-year contract that can be terminated at any time with 90 days' notice.³

In the early years, there were few other professional services offered as franchised businesses. But that changed during the second wave of franchise growth that began in the 1990s.

2. The Second Wave: The Rise of Senior Care

The second wave of franchising in the health care professions provides a window into the unmet needs in a market. For example, during the 1990s, a number of entrepreneurs started companies that provided in-home senior companion care and services. The unmet need arose from several factors, including a relatively healthy, aging population consisting of parents of Baby Boomers, and Baby Boomers themselves who lived a long distance from their parents. These parents were not ready or interested in transitioning to a nursing home or assisted living facility. They were people who were capable of living independently, but wanted either companionship or some assistance with daily tasks.

The Senior's Choice is a typical company that provides services in this arena. The company is described as follows on Entrepreneur.com: *"The Senior's Choice is a nonmedical senior care franchise. The company offers personal care, companionship, meal preparation, light housekeeping, medication reminders, Alzheimer's care and supervision, and other services, to seniors and others in their homes to help them remain living independently."*⁴

Unlike the early innovators (e.g., Miracle-Ear and Pearle Vision) who founded a company first and then transitioned to a franchise business model after several decades, the second wave of franchised professional services began franchising almost immediately. An abbreviated list is found in Table 1.1:

³Phil Icard, a HealthMart franchisee, has said: "McKesson is going to make money by selling me more product, not by skimming off my gross. The better I do, the better they do and if HealthMart doesn't meet my expectations, I can look somewhere else. This is a franchise where my incentives and their incentives are aligned, not pushing us in different directions."

⁴<http://www.entrepreneur.com/franchises/seniorschoiceinthe/3282112-0.html>.

<i>Table 1.1 Senior Care Franchises</i>		
Company	Year Founded	Year Franchised
Home Instead	1994	1995
Homewatch Care Givers	1976	1996
Home Helpers	1997	1997
Visiting Angels	1992	1998
Comfort Keepers	1998	1999
Right at Home	1995	2000
Caring Senior Service	1991	2002
Synergy Home Care	2001	2005
Senior Helpers	2001	2005
Seniors Helping Seniors	1998	2006
Senior's Choice	1994	2007
Acti-Kare	2007	2007
FirstLight Homecare	2010	2010

Many of these brands are well known today and the fifteen listed here from *Entrepreneur Magazine's Franchise 500* have nearly four thousand units collectively and an average size of two hundred and sixty-five units per system. One of the lessons learned during the second wave by entrepreneurs in health care professions was to adopt the franchise model quickly after proof-of-concept. In many cases, the founders of these businesses had developed them with the intention of franchising.⁵

The other lesson is from economics: when a business owner has a product or service that is not differentiated in the market and there are low barriers to entry, he or she is likely to see numerous market entrants with substantially similar business models fighting for market share quickly. This potential for new franchised networks will lead to a very competitive market for recruiting franchisees.

In the third wave of health care franchising, consisting of franchising a medical service, the barriers were significantly greater – so initially, only a few companies emerged. But as workable franchise models have begun to emerge, we are seeing a rapid increase in the number of market entrants and franchise activity in health care.

3. The Third Wave: Medical Services and Other Health Care Services

The third wave of entrepreneurial growth in franchising within the health care services professions is currently under way, and continues to evolve. It is within this third wave that franchising is witnessing the application of the franchise business model to medical services. The intersection of the business model with health laws and professional rules creates a need to develop structures that are not typical for many traditional franchised businesses. As discussed in Sections II.B.1, III.A and III.B below, the corporate practice of medicine doctrine, which is designed

⁵Several of the authors and/or their colleagues have worked with one or more of the health care franchises discussed in this paper. The references to these or other companies in this paper are provided for illustration purposes only, and are not an endorsement of any particular brand or company.

to protect the health care professional's independent judgment, may result in a very substantial restructuring of the franchised business, such that the health care business that is being franchised is not the medical, dental or health care practice that provides health care to a patient, but rather the *management* of the medical, dental, and urgent care, of similar practice.

One example of a franchised company that restructured the typical franchised business model to account for the corporate practice of medicine doctrine is Doctor's Express. Doctor's Express, which was founded in 2005, began franchising in 2008. Doctor's Express is a clinic-based franchise where "each location offers urgent-care services, including treatment for acute illnesses and non-life-threatening injuries, minor surgical care, x-ray and laboratory services, travel vaccinations and pharmacy services."⁶ As stated in the Doctor's Express FDD, the franchised urgent care center is organized in the following manner: a franchisee purchases the right to open an urgent care center and after finding a suitable location and building out the center, contracts with licensed physicians who presumably form a professional corporation (or "PC"), to jointly operate the center. The franchisee has two documents that control the business: (1) a franchise agreement with the franchisor, and (2) a management agreement with the PC. (These structures, and the health law and franchise law underpinnings of these structures (including the corporate practice of medicine laws and doctrine), are discussed in Sections II.B.1, III.A and III.B, below.)

Peter Ross, one of the founders of Doctor's Express, the first company to franchise an urgent care business successfully, explains some of the challenges the company faced as the first company to franchise an urgent care business:

Forty-four states have a corporate practice of medicine law that states that the owner of a medical practice had to be a licensed physician in that state, and six states have no such statute. So we asked ourselves, 'what can be done within that framework and how can we make it work?' The franchisee is an entrepreneur and has the money and we need to protect that investment. The doctor doesn't have the money, but has the ability to create a professional corporation. Because of certain laws and regulations regarding payments and fee-sharing, we created the Management Agreement and in some cases created a consulting arrangement with a flat fee for management.⁷

The Doctor's Express FDD further stipulates that the franchisee may not provide any actual urgent care or medical services, "nor supervise, direct, control, or suggest to, the PC, physicians, or employees the manner in which the PC provides or may provide medical or urgent care services to its patients."⁸ In some jurisdictions, it may be possible for a person to both operate and manage an urgent care center, but in all other jurisdictions there must be clear separation between the franchisee and the PC, governed by the management agreement between them.⁹

⁶<http://www.entrepreneur.com/franchises/doctorexpress/333793-0.html>.

⁷See *infra* Part II.B.2.b for a further discussion of the Stark Law.

⁸Doctor's Express Franchise Disclosure Document, p.5 (2012).

⁹See for example, Doctor's Express Franchise Disclosure Document, pp. 6-7 (2012), which identified the following states as ones where the franchisee-PC distinction may not be required: Alabama, Alaska, Arizona, District of Columbia, Louisiana, Mississippi, Missouri, Nebraska, New Mexico, Utah, Vermont, and Virginia. See discussion of the corporate practice of medicine doctrine at Sections II.B.1 and III.A.1.

The Doctor's Express FDD also raises awareness of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").¹⁰ How can a medical service collect relevant patient information if the sharing of that information could result in a felony conviction? Ross states:

We [the franchisor] look at patients per day, revenues per patient, where people come from, repeat visits, and we also look at the coding so that we can understand the most common reasons for visits. But we never look at patient data. At Doctor's Express the franchisee clearly has responsibility for operations of the urgent care center – the systems and processes, billing and collections, office management, marketing and advertising and the multiple other tasks that are necessary to creating and sustaining a profitable practice. The PC (in most states) provides the medical services. Because the Doctor's Express franchisee receives access to patient data from the PC in order to provide its business services to the PC, the Doctor's Express franchisee and the PC enter into a business associate agreement to account for HIPAA compliance.¹¹

Other entrepreneurs who are following this path include Dr. Steven Poulos, founder of Primary Dentist (2012) who states:

We have the answer to building a dental practice, and will provide you with marketing and advertising programs to bring new patients in the door. Our dental model outperforms the average dentist by a substantial multiple. . . . There is no need to be overburdened by office systems and procedures; we have researched and proven the best office systems and software. For dental equipment, we will help arrange financing and discounts.

The authors anticipate more concepts to emerge in the health care space similar to Doctor's Express, with a franchise agreement between the franchisor and franchisee, and a management agreement between a franchisee and a PC, or like Primary Dentist where current dentists convert their practice and utilize the systems and tools to improve their bottom line metrics.¹²

B. The Future of the Health Care Marketplace

This biggest driver that impacts change in health care is cost, both collectively as a society and individually. Current spending in the United States on health care tops \$2.8 trillion and although annual spending increases have fallen from over 9% in the early 2000s to 3.7% in 2013, the per capita expenditure is \$8,195. With an aging population and an expected 3.5% to 4.5% increase in taxes due to the Affordable Care Act, many innovations that streamline operations and reduce costs will be forthcoming, and this is where we anticipate the most significant growth in franchised concepts.

¹⁰See *infra* Section II.B.3 for a more detailed discussion of HIPAA.

¹¹See *infra* Sections II.B.3.c and III.B.3 and Appendix F for a detailed discussion of a business associate and a business associate agreement.

¹²FRANdata reports that during the period 2006 through 2009, total unit growth in the "Health-General" sector (see Appendix A) had a 26.9% annual increase in units, and that total unit growth in the "Home Health Care" sector exhibited a 14.7% annual increase in units over the same four-year period.

Other factors that impact rising health care costs include changes in reimbursement rates and increases in insurance premiums. In addition, economies of scale in terms of equipment and supplies, marketing, and branding do not favor small practices. Finally, there is a lack of business training and the aversion of many health care practitioners, as well as the sheer lack of time, to take on the additional role of office management. The top priority for most practitioners is to help patients and provide health care.

One might speculate that we may begin seeing insurance companies leading the charge toward franchise growth. Practices that can deliver more effective results and that require less time to manage will be more profitable for insurers – potentially leading to exclusive coding or exclusive referrals for certain procedures – just as these companies have done in the past with certain automotive collision repair franchises. And since these insurance companies are looking to work with larger providers, health care practices that can provide services over broader geographic areas will be the likely beneficiaries – benefitting those practices that can expand more rapidly.

Traditional growth options, such as forming a professional partnership, do not solve the problems of office management, technology, and systems needed to operate and rapidly expand a profitable practice. For these reasons we anticipate that health care franchising will continue to proliferate. As evidence, consider Table 1.2, which shows the growth in units of franchise companies from the *Entrepreneur Magazine Franchise 500* database. We placed the companies into quartiles based on the year that the company began franchise operations and then calculated system growth from 2010 through 2013 in terms of franchised units. We also looked at the average low and average-high investment levels across quartiles.

Quartile and Year Franchised	Growth	Low Investment (\$)	High Investment (\$)
Q1: 1966 to 1997	2%	100,000	125,800
Q2: 1998 to 2005	35%	78,000	130,550
Q3: 2006 to 2007	80%	111,300	217,750
Q4: 2008 to 2013	452%	140,000	245,500

Because of the small sample size (about thirty companies in total), the authors used the median for growth, low investment, and high investment for each quartile. Table 1.2 clearly indicates that recent entrants using the franchise business model to deliver health care are not only growing significantly faster than earlier franchised companies, but require higher investment levels from franchisees.

Looking at these statistics from a market segment perspective, a similar story emerges, told in a different fashion. Growth in the first wave (product distribution franchises) over the last three years has been slightly negative. Growth in the second wave (senior care franchises), while still robust, has slowed to about 15%. But the real explosion has come in the third wave, with the

categories of medical (200%), staffing (105%), therapy (61%), and chiropractic (60%) leading the way in growth over the last three years.

But this is only part of the story: the other reason that there is a proliferation in franchised concepts within the health care industry is that franchising affords the innovator a way to monetize their efforts more quickly. As a case study, consider Brightstar, a company that was founded in 2002 and began franchising in 2005, and one that we see in the third wave. Brightstar provides staffing services to the health care industry and states in their franchise disclosure document that "you will operate an office providing supplemental health care staff to institutional clients and comprehensive care and medical services to home care clients within their home." Brightstar has several entities providing various products and services to the franchisees and the franchised network, and these create revenue streams for each affiliated Brightstar entity. The result for Brightstar? Revenues of \$10,879,789 for Brightstar Franchising and \$1,641,640 for Brightstar Technology in 2011 – just six years after starting with the franchise business model.

This begs the question, why aren't more professionals within the health care industry embracing the franchise business model to reduce costs, generate wealth, and create employment opportunities for others?

C. Misconceptions of the Benefits of Franchising in the Health Care Industry

The reason why the health care segment of the U.S. economy has been slow to adopt the franchising model most likely stems from certain misconceptions regarding franchising. First, the health care segment often perceives franchising as a business model that can only be applied to businesses where an owner-operator is required and is not appropriate for professional services, and there are few avenues available to an interested health care professional to learn about franchising and understand the benefits and applicability of the model to their business.¹³

Second, franchising has not made a deep impact within the health care profession because of the long-held view that health care providers work in practices, not businesses. It may seem like semantics, but professionals who believe that they are building a practice will focus their attention on a different set of tasks than people who believe they are building a business. Moreover, people enter into the health care field to provide services to others in need, not to create Excel spreadsheets, measure and manage costs, or otherwise worry about the efficiency of their operation.¹⁴

Third, and as a direct result of a lack of general knowledge of franchising, many health care professionals do not understand the benefits of franchising. Despite common misconceptions, franchising affords the entrepreneur an avenue for low-cost expansion with franchisees supplying the capital and labor. Another benefit of franchising is the ability to harness the knowledge of a local operator, someone who understands the culture in which they operate, has a network of relationships with the local talent pool, understands the politics of their community, and has general

¹³Even today, franchising is not considered a discipline within business schools, and few universities have even one course on franchising. In fact, when making a presentation to the Marketing Department of a top tier business school, one co-author of this paper was told, "In a semester-long course on channels we wouldn't even spend 15 minutes talking about franchising."

¹⁴For example, Peter Ross observed: "Up until about five years ago nearly everyone we spoke with in the medical profession had done nothing except study medicine; now there are a few doctors with MBAs, but the vast majority know a lot about medicine and very little about running a business."

knowledge of "how things work" in their community. Those local resources are important to creating a sustainable business.

Massage Envy, the first company to successfully franchise therapeutic massage, provides another excellent case study disproving the misconceptions of franchising. Massage Envy was founded in 2002 by John Leonesio, an entrepreneur with many years of experience in the health club industry. He applied the proven health club model of recurring revenue through monthly memberships to a highly fragmented massage therapy market. At the time Leonesio franchised in 2003, massage therapy schools were flourishing. However, training focused on the technical aspects of massage therapy, and graduates entered the workforce with little or no knowledge on how to actually build a therapeutic massage practice. Leonesio's business model revolutionized the massage therapy segment, and their clinic network has grown from only two locations in 2003 to over 1,000 today. In 2011, a typical full-time massage therapist in the US earned \$21,028 including tips.¹⁵ The Massage Envy business system provides franchisees with critical tools for membership marketing, therapist recruitment, site location and overall business operations. As a result, the average unit revenues for a Massage Envy clinic location are currently \$1.35 million, a number that few independent massage therapy clinics are able to achieve.¹⁶

In addition to being able to scale up quickly through the capital of franchisees, the franchise business model allows a brand to be built faster than through company-financed growth. Brand awareness is the elixir that makes more growth possible. With brand awareness, a franchisor will generate more qualified leads of potential franchisees, the franchisor will receive better pricing for advertising and marketing, and a franchisor will receive better pricing or rebates from vendors – all of which make the franchise business model appropriate for professionals in the health care space seeking to escape rising costs and uncertainty.

One of the biggest barriers to embracing the franchise business model is not unique to the health care industry: finding qualified franchisees. Many entrepreneurs have concerns about finding franchisees, especially with an early-stage startup. Who will take a risk on a new concept? Fortunately, there are interested investors who thrive in this situation because it allows them to get in on the ground floor of a concept that could be very successful, and, in the future, they may be able to purchase more units or territories at a discount.

In addition to investors interested in a new concept, many health care professionals already have a viable concept that has been proven, as was the case for Healthsource Chiropractic and Premier Dentist. These are not innovative "blue ocean" concepts that have never been tried before, but represent examples of the application of a successful business to the franchise business model. Our belief is that many other health care professionals will consider franchising as a way to scale their business and grow revenues in the coming decade – making an understanding of the legal complexities of franchising these businesses increasingly important to the franchise practitioner.

Note, too, that the franchised concepts within the health care space are not providing advice on how to deliver medical services – Doctor's Express explicitly warns the franchisee that there is a strict boundary between the franchisee's role and the physician role. The purpose of franchising a business in the health care space is to alleviate the uncertainty or high cost that a practitioner faces

¹⁵American Massage Therapy Association Industry Study, 2012.

¹⁶<http://www.massageenvyfranchise.com/business-opportunity>.

(like staffing, in Brightstar's case), or to provide systems and tools that make the operation of the practice more profitable.

The other point about finding people to help grow a franchise concept has less to do with finding the "right" person and more to do with not awarding a franchise to the "wrong" person. The success of franchising stems in large measure from a proven system that is followed rigorously by franchisees. The creative, innovative person who wants to alter the system, "improve" the system, or "do it their way" will undermine any franchise concept. And given the lack of control over some aspects of a health care franchise that are legally necessary (because of the corporate practice of medicine doctrine), the "branding" line in the sand may be more easily blurred in these franchises unless these standards are well thought through and documented.

It is difficult to test for these qualities *a priori* to the franchise purchase, but a good franchise company will spend a lot of time in pre-purchase interviews and initial training, driving home the point that adherence to the franchise system procedures and protocols are the key to profitability, and the inability, or unwillingness, to follow the system is cause for termination.

Franchising in the professions, and especially health care, has lagged behind the adoption of the strategy in other businesses and services, but our evidence suggests that this is changing rapidly. More health care professionals are turning to franchising as a way to mitigate the risk associated with rising health care costs, and more health care professionals with a successful practice are utilizing franchising as a way to help other professionals create a sustainable and profitable practice. As a case in point, Peter Ross, who started and sold both Senior Helpers and Doctor's Express, has embarked on another medical franchise: UnTattooU (www.untattooou.com) for the removal of tattoos. In explaining the underlying business rationale for the concept, Ross said: "This is a service for people who have regrets or have just aged and no longer want the tattoo. But since we use a laser to remove the tattoo in some states our process is considered a medical procedure. You can design around a lot of things, but you really have to understand what services you'll be providing and what the legal implications are, state by state."

It is perhaps worth remembering, that in the 1970s, the home real estate sales agents and broker industry segment was highly fragmented. At that time, franchising represented about one percent of the market, and many professionals believed that it was their relationships with buyers and sellers – not the branding and services afforded by franchisors – that would ultimately win the day. Today, less than fifty years later, franchising accounts for more than fifty percent of the home real estate brokerage market.

Predicting the future of franchising in the professions in fifty years is certainly not worth much today. But one thing is clear: franchising in the health care professions is exploding. And it would thus behoove any franchise attorney to become familiar with some of the pertinent health care issues that will confront them if they want to participate in that growth.

II. HEALTH LAWS

As noted in Section I of this paper, health care and health-related franchises have been experiencing rapid growth in recent years. Section II of this paper provides a high-level overview of health laws and regulations. Specifically, in Section II.A of this paper we discuss health law in general and identify certain laws, regulations and requirements that may impact franchising. For example, Section II.A includes, among other things, a discussion regarding the requirements of governmental payer programs, licensure and accreditation requirements, fee splitting issues, and unique change of ownership requirements. Section II.B continues the discussion with a focus on

what the authors consider the three critical health law issues for franchising – the corporate practice of medicine, fraud and abuse law, and HIPAA, and their respective impact on franchising.

Not all of the health laws and regulations discussed below will be applicable to all franchised health care concepts, and some will be applicable in different ways to a franchisor and a franchisee. The intent of this section of the paper is to provide franchise practitioners (for both franchisors and franchisees) with a summary of the types of laws and regulations that may come into play, and to provide a basic understanding of health implications on the structuring and operation of health care and health care-related franchised businesses.

A. What is “Health Law?”

1. Generally

Health law encompasses all the laws which apply specifically to the health care industry as well as those laws of general applicability which present unique issues in their application to health care providers. The Center for Law, Health & Society at Georgia State University¹⁷ has defined health law as follows:

Health law is a broad and interdisciplinary field that involves any law which affects the health of individuals and the public. The health law field includes specific laws that regulate the health industry, the public’s health, and the delivery and financing of health care services. It also includes more general laws that can impact health and health care, such as corporate and tax law, environmental law, tort law, bioethics and law, constitutional law, family law, juvenile and elder law, administrative law, intellectual property law, social welfare law and international law.¹⁸

Health law became an identifiable area of practice in the 1960s following the passage of the Medicare program. Since then, the ABA Health Law Section¹⁹ has been formed, as well as an educational organization, the American Health Lawyers Association, which has over 12,500 members.²⁰

2. What Is Unique to Health Care that May Impact Franchising?

There are many laws that are unique to health care that may impact franchising and/or the nature of the franchise. These include:

a. Reimbursement

Health care providers may receive payment from many different sources, such as Medicare, Medicaid, Medicaid waiver²¹, TriCare²², the Veterans Administration, health insurance, and payment

¹⁷<http://clhs.law.gsu.edu>.

¹⁸<http://clhs.law.gsu.edu/about/health-law/>

¹⁹www.americanbar.org/groups/health_law.html.

²⁰www.healthlawyers.org.

²¹Medicaid waiver is a program where the federal government has waived the usual Medicaid requirements.

directly from the patient. Governmental payment may come from federal, state or local government. Not all services or treatments provided by a health care provider will, however, qualify for reimbursement from a governmental payer source. For example, novel technology or a new method of treatment may not qualify for reimbursement, and there are many things Medicare simply does not cover, including cosmetic surgery and LASIK.

Health care providers who wish to receive reimbursement from governmental payment sources must first enroll in the applicable program as a condition of submitting claims, and then comply with any specific program requirements in order to qualify for payment. Enrollment applies to all providers (e.g., doctors, hospitals, nurses, home health agencies), and serves as the provider's promise to adhere to all applicable health laws and regulations and to comply with all applicable program rules and regulations. The specific program requirements, however, may only apply to certain classes of providers. For example, to participate in the Medicare program, most organizational providers (e.g., hospitals, skilled nursing facilities, and home health agencies) must meet certain conditions known as "conditions of participation."²³ Among other things, the conditions of participation may establish requirements for how and when outside managers may be used and the qualifications of employees and owners.

b. Licensure, Certification, Registration and Accreditation

Health care providers, whether individuals or organizations, are often required to be licensed, certified, registered or accredited before they may provide services. These requirements are primarily a matter of state law,²⁴ and what is required for each will vary from state to state. The terms licensure, certification, registration and accreditation mean different things, as described below.

"Licensure" refers to the process by which the government grants the individual or organization the right to engage in an occupation after verifying the individual or organization has met certain criteria. Licensure is of two types: practice protection and title protection. Practice protection licensure prohibits unlicensed persons from practicing a particular profession or operating a particular type of health care facility. Commonly, it prohibits the use of certain titles or descriptions, such as M.D., physician, or dentist, unless the individual or facility is licensed. Title protection licensure protects only the use of certain titles or descriptions unless the person or facility meets certain requirements. Title protection licensure does not prohibit practice of the profession or operation of the type of health care facility as long as the prohibited title or description is not used in conjunction with it.

"Certification" generally refers to the process, typically voluntary, by which a non-governmental organization grants recognition to an individual who has met predetermined

²²TriCare is a federal government program that provides health care for members of the military and their families.

²³42 C.F.R. §§ 482.1-498.103 (2014).

²⁴For example, the Consumer-Patient Radiation Health and Safety Act of 1981, 42 USC 10001 *et seq.*, requires the Secretary of Health and Human Services to establish standards for the accreditation of programs for the education of certain persons who administer radiologic procedures in federal agencies or institutions and for the credentialing of such persons. The occupations affected are radiographer, dental hygienist, dental assistance, nuclear medicine technologist, and radiation therapy technologist. The established standards for each are at 42 C.F.R. Part 75. In addition, to encourage the administration of accreditation and certification programs by the states, it requires the Secretary to prepare and transmit to the states a model statute for radiologic procedure safety. 42 USC 10005. Adoption of the model statute is not mandatory.

requirements established by that organization. It serves to identify for the public that the individual has demonstrated competency in the occupation involved. Certification may be stand-alone, such as certification as an emergency medical technician (“EMT”), or may be used in combination with licensure, such as a physician who is licensed to practice medicine but also obtains certification by the American Board of Radiology.

“Registration” generally means that a person’s name is included on a list or registry, which serves as evidence that the person has met certain conditions. The list can then be accessed by health care providers and others to determine whether an individual is qualified for a particular job. A common example is a government maintained list of home health aides.

Finally, “accreditation” is a non-governmental process that evaluates organizations and grants recognition to those who have met the accrediting organization’s standards. For the most part, accreditation is voluntary, but certain providers and companies – advanced diagnostic imaging providers and durable medical equipment companies for example – are required to be accredited. When accreditation is required, regulators identify only certain organizations as “approved” accreditation organizations. The specific required accreditation organization will depend on the type of health care provider. Examples of health care accrediting organizations are the Joint Commission on Accreditation of Health Care Organizations (formerly known as “JCAHO”, but now referred to as “The Joint Commission”)²⁵ and the Community Health Accreditation Program (“CHAP”).²⁶

c. Fraud and Abuse Prohibitions

Both federal and state governments have become very aggressive in pursuing and prosecuting health care fraud. The prohibitions range from prohibiting kickbacks for referrals to submission of false claims. These prohibitions have a large impact on the operation and marketing of a health care franchise. What is perfectly lawful outside of health care may be unlawful with criminal penalties when undertaken by a health care provider or organization. The various health care fraud and abuse laws are addressed in detail in Section II.B.2 below.

d. Fee Splitting Prohibitions

Fee splitting refers to the practice of a professional sharing part of his or her fee for a professional service with the person who made the referral. It also can refer to a professional practice paying a portion of the professional’s fee to a management company that manages the professional’s practice. Fee splitting may be prohibited under state law or allowed only if certain conditions are met. Depending on the circumstances involved, it also may violate the federal anti-kickback statute.²⁷ As discussed in Section III.B.1.b below, fee splitting prohibitions may implicate the services provided by a franchisor for its franchisees and the fees paid by franchisees to the franchisor.

²⁵www.jointcommission.org.

²⁶www.chapinc.org.

²⁷ See Section II.B.2.a for a discussion of the anti-kickback statute.

e. Corporate Practice of Medicine

State law may prohibit the “corporate practice of medicine.” The corporate practice of medicine doctrine (or “CPM”) prohibits a business owned by non-professionals from practicing medicine either by itself or through employed physicians (and, in some states, independent contractor physicians and “physician extenders” such as nurses, physician assistants, dentists and chiropractors depending on the scope of the applicable state corporate practice of medicine doctrine). This prohibition is based on the belief that non-licensed entities should not be permitted to become involved in the professional practice of medicine. As suggested by some of the health care franchise examples described above, the corporate practice of medicine doctrine can have a significant and wide-ranging effect on the structure of the franchise system and the franchisor-franchisee-professional relationship. See discussions at Sections II.B.1, III.A, and III.B below.

f. Business Organization

Related to the corporate practice of medicine doctrine is the broader question of the types of business entities permitted to be formed by health care professionals. State law may place limits on the options available to health care providers. For example, only certain licensed professionals may be permitted to form a professional corporation or a form of limited liability entity.

As with the corporate practice of medicine, state law may affect the nature of the business entity a health care professional or organization may form, who may be owners of the entity, and whether non-professionals may be owners.

g. Certificate of Need Requirements

Certificate of need (“CON”) laws were first passed in the 1960s by states in the hopes they would slow the increasing costs of health care. The federal Health Planning Resources and Development Act of 1974²⁸ then required all states to have processes in place to require approval from a health planning agency before implementing any major capital improvements or purchase of new high-tech devices. This approval was called a “certificate of need.” The federal requirement was repealed in 1986, but certificate of need laws remain in place in approximately 36 states although they may apply to fewer kinds of projects than the original CON laws.

A state’s CON laws, if any, may restrict the establishment or sale of certain kinds of health care or health-related franchised businesses that are or will provide health care services.²⁹

h. Change of Ownership Restrictions and Requirements

What would be a straightforward business transaction outside of the health care field can become rather complex when a health care business is involved. What a franchisor or franchisee wants to do quickly may take many weeks due to required government approvals. For example, CON requirements and Medicare, Medicaid or other health care reimbursement programs may require prior notice or approval of a change of ownership of a provider subject to or participating in the reimbursement program. These requirements may establish requirements for new owners --

²⁸ Pub. L. No. 93-641, 88 Stat. 2225 (repealed 1986).

²⁹ See, for example, Kentucky’s certificate of need law, KRS 216B. A certificate of need is required to establish many types of health facilities, including a home health agency, chemical dependency program, outpatient clinic, or ambulatory surgical center.

e.g., criminal background checks, and limitations on billing until the change in ownership is processed by the government agency involved. As discussed further in Section III.B.1.c, franchisors may want to consider these extra requirements when crafting franchise agreement transfer provisions.

i. Privacy Laws

Federal and state laws which address the privacy and security of individually identifiable health care information can impact the sharing of information by a franchisee with the franchisor and the legal obligations of both the franchisee and the franchisor. The primary law in this regard is HIPAA although similar laws exist in many states. HIPAA is specifically addressed later in Section II.B.3 of this paper.

3. Examples Of Health Care Providers

Health care providers may be individuals or organizations, and may be either non-profit or for-profit.³⁰ Some of the health laws and regulations will apply to individual health care providers, some will apply to organizations and entities, and some will apply to both. For example, certain of the certification and licensure rules will apply to the individual provider that is providing the care to the patient (e.g., urgent care physician or home health nurse), while others will apply to the facility (e.g., the urgent care facility and office) or the organization (e.g., the personal service agency).

B. Critical Health Law Issues For Franchising

Depending on the nature of the health care franchise and the state involved, numerous legal issues unique to health care may need to be considered. However, there are three areas of general application that can significantly affect many health care franchising arrangements: the corporate practice of medicine, fraud and abuse laws, and HIPAA.

1. Corporate Practice of Medicine

The corporate practice of medicine doctrine may be the single most influential law or regulation that affects franchising in the health care professions. As noted, it is designed to insulate a health care professional from the influence or advice (however well-intended) of a person who is not a licensed health care professional. While the name may be deceiving, the corporate practice of medicine doctrine may, depending on the state, cover more than just physicians and the practice of medicine. Physician extenders, such as nurses and physician assistants, as well as dentists and chiropractors may be covered by a state's corporate practice of medicine doctrine. Consequently, the typical franchisor entity, which generally wishes, and needs to, establish and enforce certain operational standards, may not be able to do so if the franchisees, or franchised businesses, provide health care services.

Some states have made exceptions to the doctrine. For example, the concept of professional corporations arose to give physicians the benefit of incorporation while allowing the professional corporation to employ physicians without violating corporate practice of medicine prohibitions. Other states permit employment of physicians by an entity not owned by physicians if the entity does not directly or indirectly practice medicine through its relationship with the

³⁰ See *infra* Appendix B for a list of examples of individuals and entities or organizations that are health care providers which may be subject to these health laws.

physicians— i.e., it must not indirectly practice medicine due to its control over the employed physicians.³¹

The corporate practice of medicine doctrine can affect the structure of the franchised business entity, who may serve as an owner, and the type and degree of control exercised or permitted to be exercised by the franchisor. Because the corporate practice of medicine doctrine is a matter of state law, the way to address these issues will vary from state to state.

The implications of the corporate practice of medicine doctrine on franchising are significant:

- It restricts and limits who can serve as an owner/operator of a health care franchise.
- Because the corporate practice of medicine is designed to insulate a health care professional's judgment, it limits the control a franchisor can assert over the delivery services and products offered by the health care franchise.
- The corporate practice of medicine rules result in a separation of the true medical services and business/management services of the franchised business.

The impact of the corporate practice medicine on the structure of franchise systems, the nature of the business being franchised, and on the critical contracts governing the relationship of the parties is discussed in Sections III.A and III.B below.

2. Fraud and Abuse

Anyone dealing with the health care industry must be aware of the various laws dealing with fraud and abuse in health care. Both federal and state governments have become very aggressive in recent years pursuing and prosecuting health care fraud. Prohibitions range from prohibiting kickbacks for referrals to submission of false claims and can have a large impact on the operations and marketing of a health care franchise. During Fiscal Year 2013, for every dollar spent on health care-related fraud and abuse investigations, the federal government recovered \$8.10.³² During that same fiscal year, the government's health care fraud prevention and enforcement efforts recovered a record-breaking \$4.3 billion.³³

There are primarily five federal laws of general applicability³⁴ which deal with health care fraud and abuse and impact franchising of health care providers and their management: the federal

³¹ See, e.g., Alabama (2001 Ala. Op. Att'y Gen. 089), Iowa (Iowa Op. Att'y Gen. 91-7-1 (July 12, 1991)), and Louisiana (Louisiana State Board of Medical Examiners Statement of Position "Employment of Physician By Corporation Other Than A Professional Medical Corporation" (Sep. 24, 1992, reviewed March 21, 2001)).

³² See Press Release, U.S. Department of Health and Human Services, Departments of Justice and Health and Human Services announce record-breaking recoveries resulting from joint efforts to combat health care fraud (February 26, 2014), available at <http://www.hhs.gov/news/press/2014pres/02/20140226a.html>.

³³ *Id.*

³⁴ There are other federal statutes that can impact certain kinds of health care providers. For example, the Anti-Solicitation Statute, 42 U.S.C. § 1395m(a)(17) prohibits a supplier of items reimbursable by the Medicare Program from contacting a Medicare beneficiary by telephone concerning the furnishing of Medicare covered items except under very limited circumstances expressly stated in the law.

anti-kickback statutes; the Stark law; false claim statutes; civil monetary penalties; and exclusion. Similar prohibitions may exist at the state level.

a. The Anti-Kickback Statute

The federal anti-kickback statute establishes criminal penalties for any person who knowingly and willfully offers, pays, solicits, or receives any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for or to induce:

- (1) Referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a federal health care program;³⁵ or
- (2) Purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a federal health care program.³⁶

While the anti-kickback statute clearly prohibits payment for patient referrals, its prohibitions go far beyond such a kickback or bribe. For example, the anti-kickback statute is not limited to arrangements whose primary purpose is to induce or reward referrals. It applies to any offer, payment, solicitation or receipt of remuneration even if only one of the purposes is to induce or reward referrals; it does not have to be the only purpose.³⁷

The anti-kickback statute can apply to business relationships and investments as well. For example, a home health agency that completes a physician's paper work for a referral to the agency may violate the anti-kickback law. Or, renting office space from a referral source could be a violation.

Violation of the anti-kickback statute is a felony punishable by a maximum fine of \$25,000, imprisonment of up to five years, or both.³⁸ Conviction also results in automatic exclusion from participation in Medicare, Medicaid, and other federal health programs.³⁹ In addition, violations of the anti-kickback statute are subject to civil monetary penalties.⁴⁰

Due to the breadth of the anti-kickback law's prohibitions, the statute itself,⁴¹ and the anti-kickback regulations⁴² establish certain exceptions so it does not apply to what the government

³⁵42 U.S.C. § 1320a-7b(b) (2012).

³⁶42 U.S.C. § 1320a-7b. A "Federal health care program" means "... any plan or program that provides health benefits, whether directly or otherwise, which is funded directly, in whole or in part, by the United States Government." These include programs such as Medicare, Medicaid, and TriCare.

³⁷See, e.g., *United States v. Greber*, 760 F.2d 68,69 (3d Cir. 1985).

³⁸42 U.S.C § 1320a-7b(b)(1) -(2) (2012).

³⁹42 U.S.C. § 1320a-7 (2012).

⁴⁰42 U.S.C. § 1320a-7a-7a(a)(7) (2012).

⁴¹42 U.S.C. § 1320a-7b(b)(3) (2012).

⁴²41 C.F.R. § 1001.952 (2014).

believes are legitimate business arrangements. These “safe harbors” include, among others: investments in a health care provider, rental of space, rental of equipment, personal service and management contracts, referral services, discounts, bona fide employment relationships, coinsurance and deductible waivers, price reductions offered to health plans, and investments in ambulatory surgical centers.⁴³

Each safe harbor has a number of conditions that must be met before the safe harbor applies. If all the conditions are met for a safe harbor, the arrangement is lawful even though it might otherwise be thought to violate the anti-kickback statute. However, not meeting all the conditions does not mean the arrangement is illegal; it simply does not have the protection of the safe harbor.

A few examples of the kinds of arrangements that could violate the anti-kickback statute follow.⁴⁴

- A provider paying a referral source an amount for each patient referred to the provider by the referral source;
- A provider paying a marketing company a percentage of the provider’s fees generated by the marketing company;
- Advertisements by a provider with coupons for a discount on the fees of a provider;
- A provider giving gifts to its referral sources;
- A provider renting office space from a referral source for an inflated rent; and
- A provider waiving copayments or deductibles to attract patients.

These assume the business generated includes reimbursement by a federal health program.

b. The Stark Law

The federal Stark law⁴⁵ prohibits physicians from referring Medicare and Medicaid patients to a health care provider for the furnishing of certain designated health services if the physician (or an immediate family member of the physician) has a financial relationship with that health care provider. While the Stark law is a federal law, many states have “mini” Stark laws,⁴⁶ which have similar provisions and restrictions. The health care provider may not present, or cause to be

⁴³ *Id.* § 1001.952(a)-(d), (f), (h), (i), (k), (m) and (r).

⁴⁴ A very good paper concerning marketing by health care providers was presented at the American Health Lawyers Association’s “Physicians and Physician Organizations Law Institute,” in 2013. Anna M. Grizzle & Lori S. Richardson Pelliccioni, *A Marketing Compliance Primer for Health Care Providers* (2013), available at http://www.healthlawyers.org/Events/Programs/Materials/Documents/PHY13/A_grizzle_pelliccioni.pdf.

⁴⁵ 42 U.S.C. § 1395nn(a)(1)(A) (2012). The Stark law is a federal law. State law should be checked to determine if there is a comparable state law.

⁴⁶ See, e.g., MD. CODE ANN., HEALTH OCC. §§ 1-301 – 1-307 (2013).

presented, a claim for payment for services furnished pursuant to a prohibited referral. The Stark law is a strict liability statute. Unlike the anti-kickback law, intent is not a requirement for a violation. Violation of the Stark law can result in a number of civil penalties, including nonpayment for the services provided, civil monetary penalties, and exclusion from the Medicare and Medicaid programs.

A detailed discussion of the Stark Law and its various components, obligations, and penalties, is beyond the scope of this paper. However, it is important to at least be aware of the definitions under the Stark Law, and exceptions to law, to better understand the scope of the law. For example, there are detailed definitions for physicians, designated health services, immediate family member, and financial relationship. Also, the exceptions or exclusions include exceptions to ownership arrangements, compensation arrangements, and both ownership and compensation arrangements. For more details on these definitions and exclusions, see Appendix C.

c. False Claim Statutes

A number of health care fraud and abuse laws impose civil and criminal penalties for the submission of false claims for reimbursement to government health programs. The federal False Claims Act⁴⁷ is the most well-known of the laws to combat false claims being submitted to the federal government for reimbursement of health care services. This Civil War era law was originally established to deal with corrupt military contractors.

The False Claims Act prohibits knowingly submitting or causing to be submitted false or fraudulent claims for payment by the federal government or knowingly making, using, or causing to be made or used false records or statements to conceal, avoid, or decrease an obligation to pay or transmit money or property to the federal government.

Violation of the False Claims Act does not result in criminal penalties, but the civil penalties are great - treble damages plus an additional penalty of \$5,500 to \$11,000 for each “false claim.” In fact, False Claims Act violations serve as the largest source of fraud recoveries for federal regulators with penalties potentially exceeding hundreds of millions of dollars. Further, private individuals who raise these claims often get tens of millions of dollars.

A significant aspect of the False Claims Act is represented by *qui tam* actions, in which a private individual files a complaint, under seal, alleging violation of the False Claims Act. The government then investigates the allegations, and if it believes they have merit, intervenes in the case, unseals the complaint and assumes primary responsibility for pursuing the claim. If it is successful, the original private plaintiff receives a portion of the award. If the government feels the case is without merit, it declines to intervene and the plaintiff may, but is not required to, prosecute the action.

d. Civil Monetary Penalties

The Office of Inspector General (“OIG”) of the Department of Health and Human Services may impose civil penalties on any person who knowingly submits, or causes to be submitted, certain false or improper claims. Among other things, the Civil Monetary Penalties statute prohibits

⁴⁷31 U.S.C. § 3729-3733 (2012).

filing claims for services that were not provided or for a pattern of medical or other items or services that a person knows or should know are not medically necessary.⁴⁸

Civil monetary penalties may be imposed of up to \$10,000 per item or service and in certain cases up to \$50,000 per act, as well as treble damages.⁴⁹

e. Exclusion

The OIG of the Department of Health and Human Services has the power to exclude individuals and entities from participation in federal health programs, including Medicare and Medicaid.⁵⁰ If an individual or entity is excluded from participation in federal health programs, their involvement in the health care industry is essentially over. Further, if an individual or entity is excluded, other providers may not contract with the excluded individual or entity resulting in an affirmative obligation on all parties to ensure they are not doing business with an excluded party.

In some cases, exclusion is mandatory, and in others, it is left to the OIG's discretion—i.e., permissive exclusion.

Exclusion is mandatory for individuals or entities who are convicted of any of the following offenses:

- Conviction of federal or state health program-related crimes;
- Conviction related to patient abuse;
- Felony conviction related to certain kinds of health care fraud; and,
- Felony conviction related to controlled substances.⁵¹

Exclusion is permissible for individuals or entities that are convicted of certain offenses, including, among others:

- Conviction relating to certain kinds of health care fraud;
- Misdemeanor conviction related to controlled substances;
- License revocation or suspension; and,
- Fraud, kickbacks, and certain other prohibited activities.⁵²

f. State Laws

Most states have laws addressing health care fraud and abuse. Some are similar to the federal prohibitions and some are more stringent. Some apply only when certain payers are involved, such as Medicaid. As with most legal issues, state law must always be consulted in addition to federal law. It is not unusual for a state to have laws similar to the federal anti-kickback

⁴⁸42 U.S.C. § 1320a-7a(a)(1) (2012).

⁴⁹*Id.* § 1320a-7a(a).

⁵⁰*Id.* note 29.

⁵¹42 U.S.C. § 1320a-7(a) (2012).

⁵²42 U.S.C. § 1320a-7(b) (2012).

law, prohibitions on physician self-referral, and penalties for submission of false claims for governmental reimbursement.

g. Franchise Implications

The implications of federal and state fraud and abuse laws for franchising are several:

- They restrict the types of marketing which are lawful for a health care franchisee which in turn affects the marketing requirements or expectations which may be established by the franchisor. Additionally, if a franchisor operates a web-based referral center, this limits the manner in which a franchisee may pay the franchisor for the referral. Franchisors and franchisees must remember that what is perfectly lawful marketing outside of health care, may be unlawful with criminal penalties when done in the health care industry.
- Self-referral restrictions place limitations on who should be an owner of a health care franchise. If the potential franchisee will depend on referrals from one or more of its owners, such self-referrals may be unlawful under federal or state law.
- Due to the critical importance to assure that claims for reimbursement submitted to any government health program are accurate, health care franchisees should have strict controls in place to ensure the accuracy of claims before the claims are submitted.⁵³
- Training for health care franchisees should address the significance of health care fraud and abuse laws, their impact on franchisees' marketing, and the need to assure the accuracy of their claims for payment.

3. The Health Insurance Portability and Accountability Act (“HIPAA”)

HIPAA made significant changes to the delivery of, and payment for health care in the United States. However, HIPAA is probably best known for, protecting the privacy and security of individually identifiable health information (commonly called “protected health information” or simply “PHI”).

a. The Principal HIPAA Regulations

HIPAA is implemented by very lengthy regulations which cover, in addition to other things, the privacy rule, the breach notification rule, the security rule, and penalties.⁵⁴

The HIPAA privacy rule addresses how a covered entity may use protected health information, under what circumstances the entity may disclose protected health information, individuals' rights in their own health information, and how a covered entity must notify individuals of

⁵³In the jargon of health care, such controls can take the form of a “compliance program” and are recommended by the Office of Inspector General of HHS. Information concerning compliance programs may be found at <https://oig.hhs.gov/compliance/>.

⁵⁴See 45 C.F.R. pts. 160, 162, 164 (2013).

those rights and allow them to exercise those rights.⁵⁵ Among other things, the privacy rule requires the covered entity to: (a) appoint a privacy officer; (b) adopt and implement policies and procedures designed to ensure compliance with the privacy rule; (c) train members of the entity's workforce concerning HIPAA's requirements applicable to their jobs; (d) post and provide a "notice of privacy practices" to inform patients and clients of the entity's privacy practices and the individuals' rights; and, (e) establish sanctions against members of its workforce who fail to comply with the covered entity's policies and HIPAA.

HIPAA's breach notification rule⁵⁶ requires covered health care providers to give notification to affected individuals and to the Secretary of Health and Human Services of breaches of unsecured protected health information.⁵⁷ The rule: (a) defines what constitutes a "breach;" and, (b) when and how notice of a breach must be given to affected individuals and to the Secretary of Health and Human Services.

The purpose of HIPAA security rule⁵⁸ is to ensure the confidentiality, integrity, and security of protected health information maintained on electronic media and any protected health information transmitted by media.⁵⁹ Among other things, it requires the covered entity to: (a) appoint a security officer; (b) adopt policies and procedures to prevent, detect, contain, and correct security violations; (c) implement a security awareness and training program for all members of the covered entity's workforce; (d) conduct a risk assessment of the covered entity's operations in three areas, including administrative safeguards, physical safeguards, and technical safeguards; and, (e) implement such reasonable actions as are appropriate to correct issues identified through the risk assessment.

b. Who is Covered by HIPAA?

HIPAA applies to "covered entities." There are three kinds of covered entities: certain health care providers; health care clearinghouses; and health plans. Additionally, and as described further in Section II.B.3.c below, the security rule and most of the privacy rule apply directly to business associates.

First, a health care provider who transmits any health information in electronic form in connection with a "HIPAA covered transaction" is covered by HIPAA. A health care provider for purposes of HIPAA means a provider of services for purposes of Medicare, a provider of medical or health services for purposes of Medicaid and "... any other person or organization who furnishes, bills, or is paid for health care in the normal course of business."⁶⁰ For the purposes of HIPAA, health care is defined very broadly as "... care, services, or supplies related to the health of an individual."⁶¹ HIPAA provides that it includes, but is not limited to:

⁵⁵45 C.F.R. § 164.500 *et seq.* (2013).

⁵⁶45 C.F.R. § 164.400 *et seq.* (2013).

⁵⁷Protected health information is "unsecured" if it has not been secured by use of technology or methodology specified in guidance of the Secretary of HHS. 45 C.F.R. § 154.402 (2013).

⁵⁸45 C.F.R. § 164.302 *et seq.* (2013).

⁵⁹*Id.*

⁶⁰45 C.F.R. § 160.103 (2013).

⁶¹*Id.*

- (1) Preventive, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body; and
- (2) Sale or dispensing of a drug, device, equipment, or other item in accordance with a prescription.⁶²

A “HIPAA covered transaction” refers to “... the transmission of information between two parties to carry out financial or administrative activities related to health.”⁶³ It includes such things as health claims and similar transactions, health care payment and remittance advice, enrollment and disenrollment in a health plan, and first report of injury.⁶⁴ The most common transaction which results in a provider being covered by HIPAA is the electronic submission of claims for reimbursement.

The definition of a “covered health care provider” for purposes of HIPAA is so broad that it includes many individuals and organizations that may not think of themselves as being health care providers, e.g., providers of companion care. A health care franchisee can very easily be a covered entity for purposes of HIPAA. If so, it must comply with all of HIPAA’s requirements.

Second, a “health care clearinghouse” is defined to mean:

... a public or private entity, including a billing service, repricing company, community health management information system or community health information system, and “value added” networks and switches, that does either of the following functions:

- (1) Processes or facilitates the processing of health information received from another entity in a nonstandard format or containing nonstandard data content into standard data elements or a standard transaction.
- (2) Receives a standard transaction from another entity and processes or facilitates the processing of health information into nonstandard format or nonstandard data content for the receiving entity.⁶⁵

Depending on the services it provides for its franchisees -- for example, billing services, processing or facilitating nonstandard health information that a franchisor receives from franchisees

⁶²*Id.*

⁶³*Id.*

⁶⁴For a complete list of “HIPAA covered transactions”, see 45 C.F.R. § 160.103 (2013), which are further explained at 45 C.F.R. §§ 162.1101 – 162.1603 (2013).

⁶⁵“Standard” and “nonstandard” transactions refer to standards adopted by HHS for certain electronic transactions. 45 C.F.R. § 160.103 (2013).

into a standard electronic format or data content or vice versa⁶⁶ -- a franchisor could become a health care clearinghouse. As a health care clearinghouse, it would need to comply with many, but not all, aspects of HIPAA.

Finally, a health plan is one of many kinds of plans and programs identified in the HIPAA regulations.⁶⁷ In the context of franchising, the most common is a group health plan.

It is unlikely either a franchisor or franchisee would be a health plan for purposes of HIPAA. However, if either a franchisor or a franchisee establishes a self-insured health plan, that self-insured health plan must comply with many aspects of HIPAA.

c. Business Associates

A HIPAA concept that is very important to both health care franchisors and franchisees is that of “business associates.” Covered entities must have agreements with their business associates which address specific issues, requirements or concepts required by HIPAA.⁶⁸

It is the obligation of the covered entity, not the business associate, to obtain the business associate agreement. It is the obligation of a business associate, not the subcontractor, to obtain a business associate agreement from each of the business associate’s subcontractors. A business associate is defined, in part, as follows:

... business associate means, with respect to a covered entity, a person who:

- (i) On behalf of the covered entity ..., but other than in the capacity of a member of the workforce of such covered entity... creates, receives, maintains, or transmits protected health information for a function or activity regulated by [the HIPAA regulations], including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, patient safety activities ... billing, benefit management, practice management, and repricing, or
- (ii) Provides, other than in the capacity of a member of the workforce for such covered entity, legal, actuarial, accounting, consulting, data aggregation [as defined in the privacy rule], management, administrative, accreditation, or financial services to or for such covered entity, ... where the provision of the service involves the disclosure of protected health information from such covered entity ... or from

⁶⁶“Standard” refers to a transaction that complies with the standards adopted by the Secretary of Health and Human Services in 45 C.F.R. Part 162, see 45 C.F.R. § 162.103.

⁶⁷*Id.*

⁶⁸What must be included in a business associate agreement is listed in 45 C.F.R. § 164.504(e) (2013).

another business associate of such covered entity ... to the person.⁶⁹

There are several ramifications of the business associate concept for both franchisees and franchisors in the health care industry. These include the following:

- If the franchisee is a covered entity, it must have a HIPAA-compliant business associate agreement with all of its business associates.
- If a franchisor creates, receives, maintains, or transmits protected health information from a franchisee, the franchisor may be a business associate of the franchisee.
- If the franchisor is a business associate of a franchisee, the franchisor, itself, is subject to HIPAA and must comply with the HIPAA security rule and parts of the HIPAA privacy rule. It also must have HIPAA compliant business associate agreements with all of its own business associates.
- If a franchisor is a health care clearinghouse, any subcontractors of the franchisor that creates, receives, maintains, or transmits protected health information for or on behalf of the franchisor may be business associates of the franchisor. The franchisor must have business associate agreements with each of those subcontractors.
- If the franchisor is a business associate or a health care clearinghouse, an attorney who provides legal services to or for the franchisor which may involve disclosure of protected health information from the franchisor or on its behalf, is a business associate of the franchisor. If so, the franchisor must have a business associate agreement with the attorney.

d. HIPAA's Penalties

Covered entities and business associates may be audited by the Secretary of Health and Human Services at any time to determine their compliance with HIPAA's requirements. Covered entities and business associates that fail to comply with HIPAA's requirements are subject to civil monetary penalties and criminal penalties. Enforcement may occur either by the federal government or by state attorneys general. Civil monetary penalties are levied pursuant to a three tier system of penalties. All tiers are strict liability - the penalties are levied simply because the violation happened. A summary of the three tier system of penalties can be found in Appendix D.

e. Franchise Implications

The implications of HIPAA for franchising can be quite extensive. Most health care franchisees will be covered entities for purposes of HIPAA. This means they must comply with the HIPAA privacy rule, breach notification rule, and security rule.

If the franchisee is a covered entity, HIPAA restricts the franchisee from disclosing protected health information to its franchisor unless the franchisee has a business associate agreement with

⁶⁹45 C.F.R. § 160.103 (2013).

the franchisor. Further, even if a business associate agreement is in place, HIPAA restricts what a franchisor may do with the PHI. For example, even if a business associate agreement is in place, a franchisor may not use PHI to directly market to patients or sell patient information.

Lastly, depending on the services the franchisor provides to its franchisees, the franchisor could become a health care clearinghouse which requires it to comply with most of HIPAA's requirements.

* * *

The health care industry is diverse, complex and heavily regulated. As discussed above (albeit with a non-exhaustive summary), the health laws and regulations, at the federal and state level have a significant impact (if not burden) on a wide variety of health care and health care-related businesses, even if these businesses or practices are solo practices or not affiliated with a chain, multiple offices, or a franchised network. As we have seen, these health laws and regulations have some very specific and significant implications for franchise systems. The following section of the paper discusses in greater detail the impact on health care franchises, and how to address these issues.

III. FRANCHISED BUSINESSES

Section I of this paper addressed the rapid growth of health care and health-related franchises in recent years, and Section II addressed the unique facets of health law that franchised businesses and networks are likely to encounter. Section III of this paper analyzes the impact health law has on health care and health-related franchises. First, in Section III.A, we discuss the impact these laws and regulations have on structuring the franchise system or networks, and the franchisor-franchisee relationship. For example, depending on the type of services offered by the franchised business and the applicable corporate practice of medicine doctrine, health care franchisors may need to separate the operation of managing the health care business from the delivery of health care services, and may need to limit the "products and services" offered by the franchisee to providing business support and administration to an independently owned and operated medical business.

In Section III.B, we analyze how health laws affect the various agreements that will govern the health care franchise relationship. For example, contractual provisions such as product or service sourcing restrictions which are common in the franchise industry may need to be revised or eliminated in light of applicable health laws. Likewise, additional contracts and agreements may be necessary, depending on the franchised business structure and the services provided. Section III.C continues with a discussion of the impact health laws may have on the day-to-day operation of the franchised business. Finally, Section III.D concludes with a summary of the FDD disclosures that may be affected by the various health laws and regulations, and the actions taken by, or perspectives of, some state franchise examiners in evaluating franchise registration applications of health care or health-related service franchises.

A. Structures

As discussed in Section I.A above, there is no one monolithic type of health care franchise. There are approximately 100 industries or business sectors that utilize franchising as an expansion

method, or a product or service distribution model,⁷⁰ and approximately 10 to 15 of those sectors may be categorized as, or considered to be, the health care, health care-related, or “healthful lifestyle” fields.⁷¹ As evidenced by the myriad of health laws discussed in Section II of this paper, the legal, statutory and regulatory restrictions and requirements may impact how a health care or health-related franchise is structured. These restrictions or limitations are not necessarily industry-specific but arise out of the type of laws or regulations that are applicable to a particular health care service or health care provider. And, these restrictions or limitations may vary from state to state.

1. Franchisee as a “Practice Manager,” not a Health Care Provider

One of the fundamental differences between what are commonly understood as traditional commercial or business format franchises (such as restaurants, hotels, muffler shops, etc.) and health care or health-related franchises, pertains to the control over the products or services that are delivered to customers or patients, and a franchisor’s ability to dictate or control the products or services offered at the franchised outlet. This distinction arises – in the health care franchises which deliver medical services in particular – from the “corporate practice of medicine doctrine.” To illustrate this distinction, let’s contrast a burger franchise with a dental clinic. The franchisee of the burger restaurant must provide the burger, with lettuce, tomato, pickle, ketchup, etc., cooked and presented in the manner required by the franchisor and the franchise system. The franchisee must utilize the kitchen equipment specified by the franchisor, and operate in a facility designed or approved by the franchisor. Under this traditional franchising model, the franchisor provides, and the franchise system or method of operation includes, instructions, requirements, or controls regarding the delivery of the product (e.g., hamburger) to the customer. Certain elements of this control are designed to establish consistency among outlets and the development of the consistent brand message.

Turning to the dental clinic franchise, a franchisor may not be able to exercise the same control over the delivery of the products or services to the patient. As discussed above in Section I, and at Section II.B.1, the state laws prohibiting the “corporate practice of medicine” may have a significant impact on the structure of a health care franchise. Specifically, a health care practice or business that is owned by someone who is not licensed to provide those professional health care services may not practice medicine, nor be involved in the practice of medicine. While the rules vary by state, and they vary among different medical specialties depending on the particular medical discipline involved, as noted above, the general purpose is to prevent non-licensed professionals from influencing the professional judgment of the doctors, dentists, or other licensed health care providers. To contrast this type of franchise with the burger franchise, the dentist at the franchised dental clinic must be free to determine her recommended course of action for each patient – whether to x-ray a tooth, fill a tooth, prescribe certain drugs, etc., without influence or control by the franchisor. Regardless of whether that dental clinic is affiliated with a franchise brand or not, the dentist decides how to treat the patient.

⁷⁰According to the International Franchise Association’s website, www.franchise.org/franchise_categories.aspx, as of July 28, 2014, IFA identifies 98 industries or business category segments for which IFA publishes franchise opportunity information.

⁷¹As noted above (see discussion at footnote 1), some health-related services or products are only minimally related to health care, such as weight loss programs and fitness centers. See also Appendix A. Of the 98 industries on the IFA website, less than 10 fall under a generally recognized “health care” or “health related” field such as health services or home care.

For health care services that are subject to the corporate practice of medicine rules, the franchisor may not control the delivery of the services. Also, at the franchisee level a non-licensed or non-professional franchisee may not control or influence the services provided to patients. If a franchisor may not influence the professional decision of the franchised health care business, and if a franchisee that is not a licensed professional cannot influence the professional decisions of a health care franchised business, then what business is being franchised? In many situations, the health care business that is being franchised is not the medical, dental or other health care practice. Rather, it is the management of the medical practice, the dental clinic, the urgent care, or a similar physician-operated business.

In the situations in which a possible franchised health care business is subject to the corporate practice of medicine, the franchisor must make two fundamental decisions. First, what service or business will be franchised? Second, who will be the owner or the franchisee? The first question may seem odd. If the “franchise” is for an urgent care, a dental clinic or a dermatology clinic, the natural assumption is that the business being franchised is for an urgent care, a dental clinic or a dermatology clinic. However, if the applicable corporate practice of medicine rules require that these practices be operated only by licensed physicians, the franchisor will not be able to dictate, control, or even influence the operations of the business, or the services provided. Therefore, in these types of health care businesses, the franchisor is likely to grant a franchise for a “practice management” business that supports a particular health care service.

The franchised business will be a business that manages a medical practice such as a dermatology practice. For example, the franchisee might be responsible for locating and establishing the medical facility, obtaining and maintaining the necessary medical equipment (e.g., x-ray equipment, on-site laboratory, exam room equipment), obtaining and installing furnishings, fixtures and equipment, etc. None of these activities, however, are associated with “practicing medicine.” The franchisee would locate one or more professionals (e.g., doctors) who would form a medical practice (in accordance with local laws and regulations),⁷² and would operate the medical practice at the location provided by the franchisee. The franchisee would execute a management agreement with the PC to provide the various management services and “back-office” support necessary to operate the medical practice. In this situation, neither the franchisee nor the franchisor dictates, controls or influences the medical or health care practice. The health care professionals are free to dispense advice, services and products, independent of franchisee or franchisor counsel, and subject to compliance with the applicable licensure and certification of their specific professions.

The corporate practice of medicine rules may affect not only the structure of the franchisor-franchisee relationship (by creating a need for the franchisee to be a “manager”), but these rules may also affect the structure or ownership of the franchisee. Because certain health care businesses may be owned only by physicians or licensed professionals, there may be an inclination to grant franchises to only physicians or licensed professionals. While this course of action may avoid the corporate practice of medicine issues faced by the franchisee, this structure may not avoid the corporate practice of medicine issues as they relate to the franchisor. Even if the franchisor will not “employ” the franchisee, or the medical professionals who are working for the franchisee, some states’ corporate practice of medicine rules prohibit the influence over, or control of, the medical practice. Because these prohibitions or limitations arise in some states, particularly

⁷²In many cases, the professionals will form a “professional corporation” or “PC” which is the entity that provides the medical or health care services.

in some larger or more populated states (e.g., California, Florida, or Illinois)⁷³, a franchisor will be severely hampered in trying to develop a national system. While a franchisor may try to establish and operate two related, but different systems, the practical, logistical and cost hurdles may be too great to do so.

The corporate practice of medicine rules are not the only laws that may affect the franchise structure or the franchise-franchisee relationship. Restrictions on payments, referral fees, and the sharing of revenue with non-physicians also affect structure. As discussed in Section III.B.1.b below, even in situations in which the franchisor-franchisee relation is not affected by the corporate practice of medicine doctrine, these fee splitting restrictions and similar rules will affect the franchise agreement.

2. Ownership of Franchised Health Care Businesses

One of the hallmarks of franchising is developing a business model that is more efficient, due to a better or lower cost supply chain and/or a better, more efficient or more robust pipeline of potential customers. A franchised health care business often operates in a small sector of an industry and improves the delivery of a particular service or product. Consequently, it is easy to see how doctors and other health care professionals may view certain health care franchised businesses as a natural extension of their practice, and therefore wish to become financially or managerially involved. For example, an orthopedist may have an interest in a mobile x-ray or imaging business, or a physician may wish to own a home health agency. At Pearle Vision, for example, it is common for the optometrist doing eye exams to own the adjacent optical dispensary. When the dispensary is owned by an optician, there are a variety of state laws that govern that relationship; and, in some states (California for example) there is a requirement for the optician to have a separate entrance from the dispensary.⁷⁴ If these franchised businesses may be owned by physicians, there should not be a corporate practice of medicine concern. However, if the physician views the franchised business as a referral source, or as a recipient of referrals, the doctor and the franchised business must take special care to not share revenues or otherwise violate the anti-kickback rules or Stark Law. Some franchisors may decide to not offer franchises to physicians and other professionals who are subject to these laws. Even if this type of ownership is permitted, the franchise agreement should explicitly proscribe the types of ownership structures that may violate a state law.

In some states, the laws permit partial ownership of a health care practice or facility by non-licensed professionals.⁷⁵ In these states, the franchisor and franchisee must be assured that the ownership structure, including the percentage of non-licensed professionals and the entity structure complies with applicable law.

In some health care or health care-related fields, for example a pharmacy, a home health agency or a hearing aid store or business may be owned by an individual or entity that is not a

⁷³CAL. BUS. & PROF. CODE § 2400 *et seq.* (2012); Op. Att’y Gen. Fla. 055-71 (Mar. 25, 1955); 201 ILL. COMP. STAT. 8/10.8 (2005); *People ex rel. Kerner v. United Medical Service, Inc.*, 200 N.E.157 (Ill. 1936).

⁷⁴CAL. BUS. & PROF. CODE §§ 2556, 3103 (2012).

⁷⁵ For example, Missouri rejected the corporate practice of medicine doctrine in 1907. *Sager v. Lewin*, 106S.W. 581 (1907). That opinion held that a corporation itself was not engaged in the “practice of medicine” by employing physician to perform medical treatment. A 1962 Missouri Attorney General opinion appears to confirm that no corporate practice doctrine exists and that contracting with licensed medical practitioners to furnish medical services does not constitute the “practice of medicine”. 1962 Mo. Op. Att’y Gen. 8 (1962).

licensed pharmacist, physician, or audiologist. However, federal or state laws may require the presence of a licensed provider during times in which individuals receive services. The state laws may require that a licensed or certified pharmacist, physician, or audiologist be on site during all times when customers are present, or that such a licensed professional oversee all operations of the business.⁷⁶ Also, although there appears to be a movement among states to directly regulate “medical spas”, the simplest reason that physician ownership and licensure can sometimes be required is because the services offered in “medical” spas, while marketed as cosmetology or esthetic services, can easily cross the line into the “practice of medicine”, thereby triggering corporate practice of medicine and physician licensure statutes.⁷⁷ In these situations, the state licensing and certification requirements may dictate to whom the franchisor may grant a franchise, and may require additional scrutiny in evaluating transfers and assignments of franchise agreements and franchisee ownership interests.⁷⁸

B. Agreement Modifications and Ancillary Contracts

Practitioners representing health care or health-related franchise systems need to be mindful of the health law issues discussed in Section II of this paper when drafting the various agreements (including the franchise agreement) that will govern a health care franchise. Before drafting, practitioners should consider: (i) the type of services being provided by the franchised business, (ii) whether federal payers will be providing any reimbursement in connection with providing the franchised services and products; and (iii) whether other ancillary agreements are necessary given the structure of the franchised business. These initial considerations are key to drafting the various agreements that will govern any franchised health care program.

1. Franchise Agreement

a. Corporate Practice of Medicine Doctrine – Restrictions on Franchisee’s Role

As discussed in Sections II.B.1 and III.A above, if the franchised business will include the provision of medical services – e.g., a physician (and, in some states, a physician extender) providing medical care, the corporate practice of medicine doctrine must be considered when preparing a franchise agreement. A common method for addressing corporate practice of medicine issues is to limit the franchised business to “providing business support and administration” to an independent medical professional corporation, or PC. Under this arrangement, the franchise agreement requires the franchisee to enter into a management agreement with a PC under which the PC agrees to provide medical care and services from the franchised business location. While often negotiated by the franchisee and PC, a form management agreement is typically included as an exhibit to the franchise agreement (or as an exhibit to the FDD), and the franchise agreement expressly requires the franchisor to approve the PC and the final terms of the management agreement prior to signing. A further discussion of the typical terms and requirements included in a management agreement can be found in Section III.B.2 below.

⁷⁶ See e.g., 42 C.F.R. 410.32(b)(3)(iii) (Medicare regulation requiring in-room presence for procedures requiring “personal supervision”).

⁷⁷ See e.g., Minn. Stats. 147.081, subd. 3(4) (defining “practice of medicine” to include “surgical operation including any invasive or noninvasive procedure involving the use of a laser or laser assisted device”).

⁷⁸ See discussion at Section III.B.1.c. regarding addressing modifications of a franchise agreement’s transfer of ownership provisions.

Because the scope of the “products and services” offered by the health care franchised business would be limited to providing business support and administration to the PC, the scope of the franchisee’s contractual responsibilities and obligations as outlined in the franchise agreement would be limited to such things as: (i) securing and constructing a location for the franchised business which meets the criteria, layout and design required by the franchisor; (ii) providing, updating and replacing all equipment, supplies and materials needed by the PC to operate the medical component of the business; (iii) providing financial, bookkeeping and accounting support to the PC; (iv) displaying and properly using the trademarks licensed to the franchisee in connection with operating the franchised business; and (v) complying with all other system standards and requirements. The franchise agreement should clearly state that the franchisee is not authorized to provide medical services or care, but rather the franchisee must contract with a PC (that is approved by the franchisor) to own and operate the medical component of the business. All decisions relating to the medical practice – e.g., hours of operation, how many patients a physician will see, and the specific medical care and services that will be provided, must be left to the PC in order to comply with applicable corporate practice of medicine issues. A sample provision from a franchise agreement in which the franchisee will serve as the management company for a health care business that provides medical services and is subject to the corporate practice of medicine is found at Appendix E.

In addition to separating the medical and business support obligations to address the corporate practice of medicine doctrine, other common provisions of a franchise agreement may need to be addressed to ensure compliance. For example, restricting the source of supply or particular product or service a franchisee may use in connection with the operation of the franchised business is quite common in the franchise industry. This restriction, however, may run afoul of the corporate practice of medicine doctrine to the extent the restriction applies to the medical equipment or supplies used by the PC.⁷⁹ While recommendations can be made concerning all medical equipment and supplies, and the franchisor can reserve approval rights, ultimately the selection of medical equipment and supplies, and the source of such equipment and supplies, must be left to the PC. Any mandate to the contrary could result in a violation of the corporate practice of medicine doctrine.

Further, all clients or patients (and their medical records) served by the PC should belong to the PC. This issue not only raises potential corporate practice of medicine issues but, as discussed Section III.B.1.d below, HIPAA and state data privacy issues may arise if a covered entity shares protected health information with a third party.

b. Federal Anti-Kickback Statute & Fee Splitting Laws

A second health care issue that may impact the drafting of a franchise agreement arises from federal and state laws regarding fee splitting and kickbacks. As discussed in Section II.B.2.a above, the federal anti-kickback statute prohibits the payment or remuneration for referrals covered by federally funded programs like Medicare and Medicaid. Likewise, state fee splitting laws prohibit a medical professional from sharing a portion of patient fees with a lay entity.⁸⁰ Given the federal anti-kickback statute and state fee splitting laws, drafters of health care franchise agreements must

⁷⁹The purpose of the corporate practice of medicine is to protect the professional judgment of a health care professional. Dictating the specific medical equipment or supplies the PC must use in providing medical care will, under most corporate practice of medicine doctrines, jeopardize the protection and insulation of the health care professional’s independence. See *supra* Part II.B.1.

⁸⁰See *supra* Part II.A.2.d for a discussion of state fee splitting laws.

be mindful of these health laws and regulations when structuring the flow of payments between the franchisor and franchisee or, in the case of a management agreement, the franchisee and the PC. In many situations, the management agreement between the franchisee and the PC will not include a percentage-based management fee, but rather a fixed fee based on the fair market value of the services provided, or a “cost-plus” basis. Some management agreements provide for the management company (that is, the franchisee) to receive all revenues from the PC’s operations, less the expenses of the PC (which would include the physician’s salaries, benefits, etc.) These structures are designed to comply with the fee splitting rules. Requiring a franchisee, however, to pay the franchisor a royalty fee calculated as a percentage of the franchisee’s gross receipts – including, receipt of the management fee is, in most instances, permissible. All of these structures should be evaluated under applicable law. Also, a franchisor may have more than one form of management agreement to address variations in federal and state laws.

Further, it is common practice in the franchise industry for referral sources to receive some form of consideration in exchange for referring the client or customer to the franchised business. Such a referral may, however, trigger a violation of the federal anti-kickback statute and/or applicable state fee splitting prohibitions depending on the relationship between the referring party and the franchised business, and whether a governmental payment is involved.

c. Federal Reimbursement Programs

An initial consideration that a health care franchisor must determine is whether its franchisees will receive reimbursement from federal reimbursement programs such as Medicaid and Medicare. If franchisee involvement in such reimbursement programs will be allowed, the franchise agreement should include language requiring franchisees to enroll in such programs and to satisfy and maintain all enrollment requirements as a condition to operating the franchised business.⁸¹ The consequence of any failure to enroll or subsequent disqualification should be addressed in the franchise agreement’s termination provision. Likewise, if enrollment in such programs is prohibited, the franchise agreement should include an express statement prohibiting enrollment.

Further, if Medicare/Medicaid beneficiaries are part of a franchise system’s client base or patient population, there will be significant restrictions on how a franchisee bills to, and collects from, these beneficiaries. One restriction in particular is that the provider cannot charge the beneficiary more than what is permitted under the Medicare benefits schedule. Therefore, the franchise agreement may include restrictions on the patients to whom the business will provide services, and/or include requirements regarding compliance with the Medicare billing and collections rules. To the extent a franchise agreement includes language regarding establishing pricing, reference to the restrictions imposed by any federal reimbursement program should be incorporated.

Finally, health care franchisors allowing participation in federal reimbursement programs should be aware of the advance notice and transfer requirements that will be imposed on a franchisee in the event of a change of ownership or transfer situation.⁸² Franchisors may want to add language to the franchise agreement’s transfer provisions requiring that all applicable federal

⁸¹See supra Part II.A.2.a for a further discussion regarding governmental payment enrollment and participation requirements.

⁸²See supra Part II.A.2.h.

reimbursement program transfer requirements and notifications be satisfied prior to the franchisor's consent to the transfer.

d. HIPAA & State Data Privacy Laws

Drafters of health care franchise agreements need to consider HIPAA regulations and state data privacy laws when drafting provisions regarding the ownership and use of client/patient data and information.⁸³ Most modern day franchise agreements expressly state that all client or customer information and data utilized by the franchisee in operating the franchised business belongs to the franchisor and may be used by the franchisor as it deems appropriate. Such contractual provisions may be problematic in the health care industry given HIPAA and other state data privacy laws. In particular, HIPAA or other state laws may prohibit the sharing of client data or information between the franchisor and franchisee, and when applicable, between a franchisee and PC.

To address HIPAA compliance, many franchisors utilize a business associate agreement to allow the sharing of such information between the franchisor and franchisee, and franchisee and PC.⁸⁴ Franchisors utilizing a business associate agreement should attach a copy of that agreement to the franchise agreement and include a provision in the agreement requiring the franchisee to sign the business associate agreement as a condition of operating the franchised business.

e. Certification, Registration & Accreditation

Finally, while most franchise agreements include a provision requiring franchisees to comply with applicable state law, to the extent a franchisee or its employees must obtain and maintain a specific certification, registration or accreditation, such requirement should be outlined in the franchise agreement. For example, if an in-home health care franchisor requires its franchisees to obtain accreditation from The Joint Commission, this requirement and the timing for obtaining this accreditation should be specified in the franchise agreement.

2. Management Agreement

As noted above, a common method for addressing the corporate practice of medicine doctrine is to require a franchisee to enter into a management agreement with a PC that will act as the owner and operator of the medical services component of the business. A form management agreement should be attached to the franchise agreement, but often will be negotiated by the franchisee and PC prior to signing. Franchisors should include a provision in the franchise agreement that requires the franchisor's prior written approval to any negotiated management agreement prior to the franchisee and PC signing the management agreement.

The terms of the management agreement govern the relationship between the PC and the franchisee. In essence, the PC provides all medical care and services to the PC's patients from the premises of the franchised business and, in turn, the franchisee provides all day-to-day business and administrative support to the PC's medical business. A franchisee generally provides the PC with certain management services (as articulated by the terms of the management agreement) and all equipment, furnishings, office space and supplies needed by the PC to provide medical care and

⁸³See supra Part II.B.3.d for a thorough discussion of the HIPAA regulations and requirements.

⁸⁴ A discussion of business associate agreements is at Section III.B.3 below, and a summary of certain terms required to be in a business associate agreement, and several optional terms, is in Appendix F.

services. In return for these services, the PC pays the franchisee a management fee. To address any corporate practice of medicine doctrine and fee splitting issues, the management fee typically reflects the bona fide amount for the administrative services provided by the franchisee and the fair market rent for the leased office space. Because the management fee reflects payment for management services provided by the franchisee and not the provision of medical services, franchisors typically charge a royalty fee based on, among other sources of revenue, the management fee without violating any corporate practice of medicine or fee splitting prohibitions.

Additionally, to address the corporate practice of medicine doctrine, a management agreement should expressly state that the PC and its employees, will have independent medical judgment with respect to all medical care and services provided to the PC's patients. As noted in the sample franchise agreement provision in Appendix E, the franchise agreement should contain a provision that "mirrors" the management agreement provisions that prohibit the franchisee from engaging in actions that belong in the domain of the licensed health care professionals. Further, the management agreement should require the PC's approval of all medical equipment and supplies provided by the franchisee and used by the PC in connection with providing medical care and services.

Management agreements typically include representations and warranties from the PC that: (i) the PC is licensed and certified by the state to provide the specific medical care services described in the management agreement; and (ii) the PC will serve as the employer of record for all employees that provide medical care or services from the franchised business location. A management agreement outlines the PC's ownership and control of all patient medical records and includes language granting the franchisee access to such information to the extent permitted by law and as necessary for the franchisee to satisfy its administrative responsibilities. As a condition of granting this access, generally the franchisee and PC will enter into a business associate agreement to comply with HIPAA-related issues.

Finally, the management agreement usually outlines any minimum insurance coverage the franchisee will obtain, at its own expense (relating to the equipment, supplies and office space used in connection with providing the medical care and services) and at the PC's expense (relating to the medical services and care provided by the PC, including medical malpractice insurance). The management agreement will outline any non-competition and non-solicitation obligations imposed by the PC's and its medical employees'.⁸⁵

3. Business Associate Agreement

To address HIPAA compliance, many health care franchises employ a "business associate agreement" which allows for the sharing of protected health information between the franchisor and franchisee and, if applicable, the franchisee and PC. The business associate agreement outlines the permitted uses and disclosures of protected health information by the business associate, and incorporates the privacy, breach notification and security obligations required by HIPAA.⁸⁶ For example, a business associate agreement used in connection with a management agreement would permit the franchisee (the business associate) to utilize the protected health information

⁸⁵State law may restrict the use of non-competes and/or no solicitation agreements involving health professionals. See, e.g., COLO. REV. STAT. § 8-2-113 (2013); MASS. GEN. LAWS ch. 113 § 12X (2014).

⁸⁶See *supra* Part II.B.3 for a discussion of the privacy, breach notification and security obligations required by HIPAA. See *also* Appendix F for contract terms that must be, or often are, included in a business associate agreement.

provided by the PC in connection with the franchisee providing business support and administration services to the PC.

A typical business associate agreement also prohibits the business associate from receiving any remuneration in exchange for sharing protected health information with a third party or from marketing to clients and customers on the basis of the protected health information. Finally, a business associate agreement requires business associates to obtain similar agreements from any third-party subcontractor who becomes a business associate of the franchisee.

C. Operational and Business Issues

Every business, in every industry, whether franchised or not, is subject to some level or degree of regulation or licensing, from certificates of occupancy, to retail food and beverage licenses for restaurants, to hair stylists' cosmetology licenses for hair salons, to the disposal of used motor oil for oil change businesses. As discussed throughout this paper, health care businesses and health-related businesses are subject to specialized regulations, laws, and licensure requirements, which are greater in number and scope than many other industries that provide products and services at a retail level to customers. Some of these health laws and regulations can fundamentally alter the franchisor-franchisee business relationship, and some may require specialized provisions in franchise agreements or even the need to create new contracts so that the franchisor and franchisee can comply with the health laws.

The wide scope of the health laws may also have a significant impact on the operations of each franchised health care business. Some of these laws, rules and regulations address pre-opening qualifications, while others impose ongoing compliance obligations. Some laws regulate the operations of the business, and/or the facilities utilized by the business, while others are designed to regulate, qualify, license or certify the individuals providing the health care service or product. This section will address many of the impacts of these health laws on the operation of individual franchised businesses. For the practitioner who is advising a franchisor in the health care industry, or a prospective franchisee of a health care business, many of these laws and regulations will not be referenced, or will not be referenced specifically, in the franchise agreement. They may be discussed, albeit briefly, in the FDD, and they may be described in the franchisor's operations manual or other operating or franchisee ownership policies. By way of comparison, a restaurant franchise agreement may not reference a food safety or food handler license, but may have a general "comply with all laws" provision, and a requirement to "obtain and maintain all licenses for the operation of the business" provision. Similarly, a health care franchise agreement may not include a litany of all required licenses and certifications required of the franchisee to lawfully operate the business. The practitioner – and preferably one knowledgeable about the health laws – should guide the franchisee through the regulatory, licensure and certification thicket.

1. Licensure, Certification, Registration and Accreditation

As discussed in Section II.A.2.b above, licensing, or licensure, is a government approval or authorization process that prohibits the use of certain titles and/or prohibits unlicensed persons to practice in a particular health care field. For example, only a dentist can be designated as "D.D.S.," or only a registered nurse may be designated "RN," and only an occupational therapist may use the "OT" designation. These are often subject to state laws, and these are some of the most commonly understood forms of licensure. A related requirement is that certain health care facilities may not be operated by individuals that do not have certain licenses. For example, under certain state laws, an urgent care facility may only be operated by a licensed doctor and a home health agency may not

be operated unless a physician or licensed registered nurse is available at all times to provide supervision and direction of skilled services.⁸⁷

The license requirements may also prescribe the scope of services that licensed professionals may offer. For example, in Minnesota, a licensed chiropractor may practice only those noninvasive means of clinical, physical and laboratory measures and analytical x-ray of the bones of the skeleton which are necessary to make a determination of the presence or absence of a chiropractic condition. This may include procedures which are used to prepare the patient for chiropractic adjustment or to complement the chiropractic adjustment. The procedures may not be used as independent therapies or separately from chiropractic adjustment.⁸⁸ Therefore, the franchisor of a chiropractic franchise must be cognizant of the limitations on chiropractic services in the states in which the franchises will be operated. The franchisor cannot require that certain services be required as part of the business if those services are prohibited by a state license. A franchisee, in this example a chiropractor at a franchised location, must comply with both the franchise system restrictions or limitations, and the requirements under the state license.

The licensure requirements vary by state and by industry. While a franchisor may not know all of the rules throughout the country, it should become at least generally familiar, if not specifically knowledgeable, about a state's licensing rules before the franchisor offers or sells franchises in that state, so that (i) it does not waste resources promoting a business that may not operate in conformity with the system, and (ii) it does not grant franchises that will either violate the system standards or franchise, or the local licensing requirement.⁸⁹

Certifications are similar to licenses, but these are generally non-governmental approvals or recognitions. While these may not be "required" by a government agency or a law, they may be required by the franchisor. Moreover, certifications often serve as a seal of approval to the public that a professional, a business, or a facility has met a certain industry or professional standard. From a franchise system perspective, the certification may be necessary to present a consistent brand message regarding the qualifications of all providers or all facilities that operate under the franchise brand name. For example, a chain of franchised dermatology clinics may require that all physicians are board certified in Mohs⁹⁰ micrographic surgery. Assuming that the franchisee is a doctor, and assuming this structure is permitted by local law, the franchisee may not hire any doctors that are not Mohs certified, or the franchisee (if a practice management entity) may not manage a PC that utilizes any non-Mohs certified physicians. Similarly, a mobile imaging business may be required to hire only American Board of Radiology certified radiologists and technicians.

Registration – that is, the process by which a health care professional is included on a professional registry based on his/her satisfaction of certain educational and professional qualifications – is yet another requirement that may be imposed by franchisors on franchisees or the health care providers employed by the franchisee or PC. While registration may not be required by

⁸⁷ See, e.g., 410 IAC 17-12-2(d) (Indiana).

⁸⁸ Minn. Stats. 148.01, subd. 3.

⁸⁹The issue of whether a franchisor is offering a franchise opportunity that may violate a state health care licensing requirement is the underpinning of some state franchise examiners' requests that franchisors demonstrate that the business being franchised complies with state law. See *infra* Part III.D.

⁹⁰"Mohs" is a type of microsurgery used to treat common types of skin cancer, and is sanctioned or approved by the American Academy of Dermatology and other dermatological associations.

law or regulation, the franchisor may require registration to set minimum standards for the system and to provide consistent brand standards for the public. And even if the standard may be generated or imposed by the franchisor, it also may be a threshold prerequisite for a franchisee or health care provider to join a system. Many franchisees will only join a system that maintains a certain level of requirements, certifications and registrations for other franchisees and franchised outlets in the system.

Accreditation is another non-governmental, primarily voluntary process that provides a third party “stamp of approval” on a health care facility or business. One of the examples mentioned above, The Joint Commission, will provide accreditation and certification for a wide variety of health care organizations⁹¹ including, among others, ambulatory health care facilities, home care organizations, laboratory services, nursing care centers, and health care staffing services. This is yet another example of establishing standards for system-wide operations that can be promoted to the public.

While licensing, credentialing and accreditation are obligations that may be imposed on the franchisee (or the professionals hired by the franchisee or PC) for the purpose of providing a consistent brand image, franchisors may also benefit from requiring system-wide compliance with governmental, non-governmental, and industry licenses, certifications and accreditation because the imposition of such obligations reduce the risk or exposure to vicarious liability lawsuits. If a problem occurs at a franchised location, and a patient is injured and sues the franchisee, there is a strong likelihood that the franchisor will also be sued under a theory of vicarious liability. One element of a defense (in addition to demonstrating that the franchisor did not control the methods or personnel that may have caused the harm) will be to demonstrate that the health care business was licensed, certified, and/or accredited by certain government or non-government industry agencies or organizations, and that the franchisee or the health care providers were following procedures established by these third-party (that is, not franchisor) organizations. These facts may not be the only, best or definitive defense, but they will support the franchisor’s argument that it did not control or dictate the process that caused the harm.

2. Credentialing

Health care credentialing is a process by which health care providers can verify to a third party their education, training and skills. Credentialing of health care providers is often a prerequisite for health insurance plans and other third-party payers to permit a provider or business into the network. From the health care provider’s perspective, becoming credentialed, or accepted, into the health care plan is necessary to obtain reimbursement for the services provided to the patients. A failure to become credentialed in one or more plans will not prohibit a health care professional from providing services, but the lack of credentials will prohibit a health care provider from being paid by the patient’s insurance plan. Consequently, obtaining the franchisor-recommended and necessary credentials before the business opens is essential. In addition, the credentialing process may take weeks or months to complete. A franchisee should be aware of the time estimate for completion of the process to better gauge when to commit funds for certain investments in the franchised business. The authors are aware of anecdotal stories of health care franchisees that committed significant financial resources toward building and developing the franchised business (including taking on large financial obligations and loans) long before they

⁹¹ According to The Joint Commission website, www.jointcommission.org, The Joint Commission accredits or certifies over 20,500 health care organizations in the United States.

started the credentialing process, which itself took months to complete. This caused the franchisee to be financially strapped from the outset.

The franchisor may (but need not be obligated to) assist with the credentialing process. Some franchisors may have staff to assist with and facilitate the credentialing process with designated health insurance networks. Some franchisors may engage credentialing assistance services (a credentialing specialist or company) to help franchisees. A franchisor should be generally knowledgeable about the process in its industry, and the timing and cost to obtain credentialing. Some of this information may be included in the FDD to better inform the prospective franchisee (see Section III.D.1 below).

3. Insurance/Government/Third-Party Payer Issues

As discussed in Section II.A.2.a, health care providers will receive payment for services from many sources, other than, or in addition to, the patient – such as Medicare, Medicaid, TriCare, the Veterans Administration, and private health care insurance companies or plans. The health care provider must satisfy certain prerequisites to obtain payment. These requirements, or conditions, relate to the qualifications of the providers; the licenses, certifications, registrations and accreditation of the providers; the practice, the business, and/or the facility; and compliance with various administrative, technical, and technology-based obligations. Consequently, the credentialing process, discussed above, is critical to the success of the franchised business.

There are other requirements embedded in certain payer programs that the franchisor and its franchisees need to take into account when establishing the business. For example, if the business intends to accept patients who will pay for services through Medicare, the health care provider must comply with all of the Medicare requirements. This includes compliance with the Stark law prohibitions on referrals, and federal anti-kickback statutes. Some franchise systems have made a determination that they will not accept (and do not want franchisees to accept) customers or patients who are Medicare beneficiaries because they do not wish to impose the compliance burdens of Medicare on their franchisees. (Generally, these sorts of limitations on patients or customers will occur in fields in which the health-related services are not “purely medical” and are not being delivered by doctors, but in fields or industries such as senior care and assistance, or certain medical technologies.) Medicare, therefore, is sometimes seen as a fork in the road for health care providers (franchised or not franchised). If, however, the franchisor makes such a determination not to accept Medicare patients, it should be communicated clearly in the franchise agreement and FDD, and in other communications with prospective franchisees.

Another aspect of the third-party payer systems is for the franchisor and each franchisee to understand the reimbursement amount of each plan or system, as well as the timing for receipt of payment. Different plans and programs may reimburse a health care provider differently for the provision of the same service, and this may vary by state. Also, understanding when a plan will reimburse the provider will allow the provider, or business, to better plan for lags in payment and dips in cash flow. This is an area where a franchisor can provide guidance and assistance to its franchisees. Franchisors can also work with government and third-party payers to assist with credentialing and approvals, to manage network relations, and to troubleshoot. Franchisors can advise franchisees which plans may be better or worse for reimbursement amounts and timing.

With the ongoing changes in the health insurance marketplace, monitoring changes and reacting to the changes efficiently will become ever more important for franchisors and franchisees.

4. Training

Franchisee training, both initial and ongoing, is crucial to the success of any franchised business. This is no different in the health care franchise model. However, the franchisor needs to clearly establish those elements of the business for which it will train franchisees, and those areas that are not subject to franchisor training, oversight, or control. This is particularly critical in health care franchises which are subject to the corporate practice of medicine rules. In these situations, the training should focus on the operations of the franchised business, and avoid the delivery of health care services and products. The training may include advice on compliance with government regulations, HIPAA, and other areas that touch on health care delivery, while not crossing over the line to health care or professional decisions. As with many other areas of franchising, the franchisor must walk a fine line between providing sufficient guidance and training to assure that a franchisee does a good job and understands how to manage and operate the business, and providing too much training, or exercising too much control to the point that the franchisor increases its risk for being vicariously liable for activities or actions of the franchised business.⁹² In health care franchises, understanding and respecting that “line” is critical, because if the franchisor crosses it the franchisor may end up exposing itself to violations of health law as well as being at risk for franchisee actions.

One way to maintain that separation is to require the franchisee, its employees, and/or the PC (if applicable), to enroll in, and successfully complete, training and accreditation programs that are offered and conducted by independent third-party organization boards, industry associations, and/or licensing boards. For example, as discussed in Section II.B.3 above, and Section III.C.6 below, HIPAA compliance is critical for both franchisors and franchisees, and a violation of HIPAA can trigger severe consequences. The franchisor could be responsible for training the franchisee on HIPAA compliance, but it might be better to require HIPAA training by a third party. HIPAA training by a third party will help assure franchisee compliance with the technical aspects of the law, as well as a governmental or industry certification, without implicating the franchisor in the training or oversight.

In virtually all medical franchises, the training should focus exclusively on the operation of the business, retail (if any) and back office functions, and should not touch on anything that could be considered “practicing medicine.” The authors, for example, are aware of one franchisor in the dermatology field, which has developed a special technique for mole removal. In this particular case, the franchisor could train the franchise owners (who are medical doctors) on the technique, but could not require them to use it because the franchise agreement was between the doctor and a non-medical franchisor entity.

In those cases where the training focuses on the practice of “business” rather than the practice of medicine, the issue of franchisee selection becomes of paramount importance. Not only is it vitally important to select franchisees that are capable of following the franchise system, but it also is important for the franchisor to be confident in the franchisee’s ability to locate and engage the best professionals to deliver the medical services well and efficiently.

5. Franchise Marketing

While there are occasional exceptions, medical franchises are generally marketed to the specific medical professional that would provide the services, such as a chiropractic franchise.

⁹²See *infra* note 95 and Section III.C.9.

Exceptions might be the “hybrids” such as auditory, skin care or vision franchises where you have a robust “retail” side of the business that can be owned by a non-medical (although licensed) professional.

In addition to the care that must be taken in marketing any franchise from a legal perspective, the marketing of a medical franchise comes with some unique opportunities and challenges. For example, when targeting franchise prospects from within the universe of medical professionals, it is often very easy to identify the qualified candidates – and given the weight that a medical degree will carry within the banking community, these candidates are often more likely to qualify for financing than would be the “typical” franchise candidate. Moreover, given the current concern among the medical community surrounding the impact that the federal Affordable Care Act might have on their medical practices, these professionals are often highly motivated to consider a franchised business as a possible avenue for operating their business while focusing primarily on what they enjoy – treating patients.

At the same time, however, some of the same characteristics and criteria that make medical professionals attractive candidates for bankers make them potentially weak franchisee candidates. Anecdotal evidence suggests that medical practitioners are generally very driven and independent “Type A” personality types. Key benefits to the franchisee business model, however, are the proven systems, policies and procedures that franchisors market and promote to prospective franchisees. If a potential “Type A” prospective franchisee is unable to see the value in the system and support offered by the franchise program, it may be more difficult to communicate the franchise value proposition as part of the marketing process. While franchise marketing can appeal to the medical provider’s desire to spend less time on paperwork and more time treating patients, the thought of buying a “franchise” is anathema to many medical professionals. Given its nonprofessional connotation (which is often associated with quick service restaurants), some franchisors targeting professionals have intentionally “re-branded” franchising under some more innocuous term (such as licensing) – while continuing to comply with franchise laws, of course – to avoid this visceral reaction on the part of prospective medical franchisees.

6. HIPAA Compliance, Data Collection and Reporting

As discussed in Section II.B.3 above, HIPAA contains wide-ranging and pervasive record-keeping, reporting and compliance obligations for health care providers and more importantly, businesses that do business with and interact with health care providers and others that have access to “protected health information” or “PHI.” The implication for franchisors and franchisees are significant.

Many health care franchises will be covered entities for HIPAA purposes. This is undoubtedly the case with franchised businesses that provide health care services. Even if one moves further away from “health care” to “health-related services,” for example, to certain home health or home care businesses, or hearing aid or medical device businesses (or even to weight loss franchises), HIPAA requirements will likely be triggered. The franchisor and each franchisee must understand the HIPAA requirements and whether the business will be a covered entity. Also, in franchised businesses, with a management company working with a PC, the franchisee/management company will almost surely be handling PHI for the PC and will be subject to HIPAA. If the franchisee, or if the franchisor through company-owned outlets, is a covered entity, these businesses must comply with the HIPAA privacy, breach notification, and security rules.⁹³

⁹³See *supra* Part II.B.3.a for a summary of the HIPAA privacy, breach notification and security rules.

Compliance requires not just knowledge of the requirements, but the designation of a privacy officer and a security officer.

Assuming the franchisee is a covered entity, the next inquiry is to understand the types of information that the franchisee may be transmitting to third parties, including the franchisor. Many franchisors will collect a vast amount of information from franchisee operations, for a variety of purposes, most of which is to monitor and evaluate the operations of each franchisee and the overall system. This data collection may include PHI. If so, the franchisor must execute a business associate agreement with the franchisee. Also, if the franchisor is involved in processing claims for the franchisee, or transmitting data (for example from a mobile imaging lab, or a drug testing facility), the franchisee is very likely handling PHI and must sign a business associate agreement. As discussed above in Section III.B.3.c, many franchisors will include a form business associate agreement as an exhibit to the franchise agreement that they will execute with each franchisee. If the franchisee desires to use that from with other business associates, contractors or subcontractors, the franchisee should be careful to modify the form to reflect the situation and the relationship. Also, the franchisor may also become a covered entity in its own right based on the data it receives, processes and transmits.

As data privacy is generally a more heightened concern for all businesses, including franchisees, health care franchises should be even more vigilant to protect their systems and networks. While some traditional, commercial franchises (e.g., restaurants and muffler repair shops) may not collect a lot of sensitive customer personal data (other than credit card numbers), a health care franchisee is likely to have access to a significant amount of highly valuable personal data, including social security numbers, addresses, and other information. The data protection software, the personnel training, and other aspects (e.g. data breach insurance) should be of a very high caliber because data thieves will recognize the value in health care businesses. Further, if there are multiple gateways to the data, through multiple franchisees, there is a greater likelihood of an error or “unlocked door.”

7. Enforcement of Standards

It is axiomatic that a franchisor must establish operational and brand standards, and enforce those standards, to maintain system-wide consistency and brand recognition in the marketplace. While this is true for health care and health-related franchises, franchisors in this sector need to be particularly careful regarding, and sensitive to, crossing the line into areas prohibited by the health laws and regulations. When it comes to brand standards, the franchisor can obviously impose all of the traditional restrictions associated with franchising. Standards pertaining to location, décor, furniture, equipment, uniforms (smocks with logos) etc. will be readily enforceable and will help the franchisor maintain its position in the consumer marketplace. But the most that a franchisor can do to control the quality of the medical care being provided is to rely on the state or federal licensing standards that already exist. A franchisor cannot impose standards on the medical professional (as related to the practice of medicine) that go beyond the licensing standards.

For most medical practices that are considering franchising, this should not pose any barrier to franchising. However, if a particular brand is dependent on the use of a particular procedure (such as the mole removal procedure referenced above) to maintain its position in the consumer's perception, the franchisor's ability to mandate that brand standard may well be compromised.

8. Consumer Marketing

As far as marketing services are concerned, if the franchise is owned by a medical professional (such as a chiropractor), it is common for the consumer-facing marketing to promote all the services offered in the franchised outlet. In other cases, it can be more complex. For example, in some states an optometrist can be employed by an optician – in others they cannot. So, if a vision franchise is owned by an optician in a “non-employment state,” the franchised business might only be able to advertise the retail side of the business. But if it is in a state that allows the employment of the optometrist and it has one in the store, it could also advertise “eye exams.”

Unlike other industries, in which the marketing campaign used to promote products or services to customers can often be left unchanged when making the transition from corporate to franchised growth, the franchisor in the health care arena needs to account for issues relative to branding as well. In some states like California, for example, the franchisee will need to apply for state approval if it wants to advertise under a fictitious name. In other states, such as Missouri and Minnesota, for example, entities formed as “professional corporations” are required to use the term “professional corporation” or “PC” in the name.⁹⁴

And, of course, when it comes to the advertising itself, there are additional restrictions. HIPAA will certainly come into play if a franchisor wants to have endorsements as a part of its advertising campaign. Moreover, at the state and federal level, direct-to-consumer advertising of medical services and devices will often come under additional scrutiny – requiring an additional level of diligence when creating ads for use by franchisees.

9. Vicarious Liability

Franchisor vicarious liability – that is, a franchisor’s liability for the actions of its franchisees – has always been a concern for franchisors, in all industry segments.⁹⁵ Consumers, franchisee employees and others will often pursue claims against a franchisor based on the argument that the franchisee was an agent of the franchisor, or that the franchisor controlled the actions of the franchisee. As more health care businesses pursue a franchising strategy we would expect that health care franchisors will not be immune from these sorts of claims.

One method that franchisors generally employ to minimize the risk of vicarious liability claims is to reduce the actual or perceived control over the franchisee’s operations. This can be done through modifying the franchise agreement to exercise control over only those brand and operational elements that are critical to maintaining brand standards. Also, franchisors should not exercise unnecessary control, by reviewing, approving or prohibiting certain activities or trying to assert authority over areas that should be left within the purview of the franchisee.

In the context of a health care or health-related franchise, the franchisor should exercise extreme caution to avoid crossing over the “line” and exercising too much control or oversight. To the extent the franchisor can rely on industry standards, or health care or professional licensing

⁹⁴Mo. Rev. Stats. § 356.071(1); Minn. Stats. § 319B.05, subd 2.

⁹⁵For a discussion of vicarious liability issues in the franchising context, see Jeffrey H. Wolf & Aaron C. Schepler, *Caught Between Scylla and Charybdis: Are Franchisors Still Stuck Between the Rock of Non-Uniformity and the Hart Place of Vicarious Liability?*, 33 FRANCHISE L.J. (FALL 2013); James Bettner, John D. Holland, Shelly Huber O’Callaghan & Kerry L. Bundy, *The Continual Threat of Vicarious Liability: Analyzing and Managing Risk*, Int’l Franchise Assoc., 46th Annual Legal Symposium (May 5-7, 2013).

standards and certifications, the franchisor can more easily demonstrate that it is not exercising unnecessary control. Vicarious liability claims cannot be avoided completely, but by utilizing the separation between professional health care services and standards, and by enforcing the business operations standards of its franchised businesses, a franchisor can reduce the risk.

D. Franchise Disclosure and Registration

The offer or sale of a health care franchise will be subject to the same franchise registration and disclosure rules as other franchises. However, due to the nature of the business being franchised, the franchise structure, the services offered, the governing agreements, and in some cases the applicable health laws, or whether franchisees enroll in federal reimbursement programs, special registration or disclosure issues may arise. These may include new or distinctive disclosures contained in a health care or health-related FDD, or enhanced scrutiny by and possible additional conditions imposed by the state franchise regulators. This Section III.D summarizes some of these disclosure and registration issues.

1. FDD Disclosures

As with any franchised business, Item 1 of the FDD includes a description of the franchise offered, including a summary of the medical and non-medical products and services to be offered by the franchised business.⁹⁶ To the extent the franchised business requires the association with a PC for the provision of medical services, this arrangement and the required management agreement should be thoroughly described in Item 1. For example, the relationship between the franchisee and PC, including a summary of their respective responsibilities and obligations under the management agreement should be disclosed. Further, to comply with any corporate practice of medicine doctrine, Item 1 should emphasize that the franchised business will not provide medical services, but rather will manage and administer the PC's independent medical practice. This would be similar to statements in the franchise agreement.

Item 1 also requires a disclosure, in general terms, of any laws or regulations specific to the industry in which the franchise business operates.⁹⁷ As outlined in Sections II and III.C of this paper, there are numerous health laws and regulations practitioners must consider when counseling a health care franchise. The Item 1 laws and regulations disclosure will depend on the products and services offered by the franchisee and whether any federal payer sources will be permitted. For example, if franchisees are required to enroll in any federal reimbursement programs or obtain a particular state license, certification or accreditation, such requirements should be disclosed in Item 1. Likewise, any HIPAA or state data privacy law compliance, should be referenced Item 1. Finally, to the extent applicable, if state health law or related regulations require a modification to the type of care or delivery of services by health care outlets in that state, such modification should be identified in Item 1. For example, if the franchise program involves providing care via the web, certain states require an initial face-to-face visit, others permit internet-based care but restrict who can provide the care, and still others require registration or permission ahead of time. Such state specifications and requirements should be addressed in Item 1.

It is important to note that not all laws will apply to all franchisees. Application will depend on the location of the franchised business. Further, the Item 1 disclosure need not be an

⁹⁶16 C.F.R. § 436.5(a)(6)(iii) (2007).

⁹⁷16 C.F.R. § 436.5(a)(6)(v) (2007); Franchise Rule 16 C.F.R. Part 436 Compliance Guide, 31 (Fed. Trade Comm'n, May 2008).

exhaustive, state-by-state, list of all laws impacting the franchised business. It should, however, include sufficient detail, descriptions and references so that a prospective franchisee will be aware of the issues and can seek counsel to learn of the details in his/her state.

If the franchised business includes the provision of medical services, in most instances, the corporate practice of medicine doctrine will apply, and that will likely result in the use of a management or similar agreement. All states have not, however, enacted a corporate practice of medicine doctrine, and, as a result, it may be possible to waive the management agreement requirement in certain states.⁹⁸ This waiver would allow for the operation and ownership of both the “medical business” and “support and administration of a medical business” by the same layperson franchisee. Franchisors allowing this waiver must, however, be diligent (and require their franchisees to be diligent) in monitoring any change to the applicable laws and regulations to ensure future compliance.

While a summary of applicable laws and regulations is all that is required by the FTC Rule, certain states may require more. For example, in connection with registering an in-home health care business, a franchise registration state may require a more thorough description of the state’s private duty licensing requirements. These requirements, if any, do not appear in state franchise laws or regulations. Rather, they may be imposed by state franchise examiners. Typically, this additional information can be disclosed in a state-specific addendum included with the FDD. Further, consideration of any state moratoria that have been or may be placed on a particular license or certification needed by a franchisee to offer a particular product or service should be considered and incorporated into any Item 1 disclosure.

Several other FDD Items may reflect specialized health care regulations or issues. For example, the additional time and expense that franchisees will incur in connection with complying with any applicable health laws and regulations, such as credentialing, should be considered when drafting the Item 7 estimated initial investment disclosure as well as the estimated “time to opening” disclosure required in Item 11. Having a clear understanding of any additional “time to opening” issues is critical for franchisees when constructing a business plan and analyzing cash flow.

As noted in Section III.B.1.a above, care should be taken when crafting any flow of payment provision to account for any illegal fee splitting or kickback issues. Drafters of health care FDDs must keep these health care-specific issues in mind when preparing the payment disclosures found in Items 5 and 6 of the FDD. For example, the definition of “gross sales” generally will not include any portion of the fees collected for providing medical services. Instead, the gross sales definition will likely include sales from all non-medical products and services provided by the franchisee. In the case of a management agreement, all management fees (assuming the management fee is limited to the fair market value of the services provided and fair market rent) will be included in the gross sales definition. These disclosures must reflect the business terms from the franchise

⁹⁸Some states may not have a corporate practice of medicine statute, or may not enforce a corporate practice of medicine doctrine by rule or interpretative opinion. This may vary by state and by medical or health care practice. See for example, Alabama (Alabama statutes and rules are silent with respect to the corporate practice of medicine; however a 2001 Attorney General opinion stated in dicta that “there is no prohibition against a physician working for a business corporation” in the state; however, a physician cannot allow a non-physician owner of a business corporation to make medical decisions. 2001 Ala. Op. Att’y Gen. 089.); Missouri (see discussion at note 75, *supra*); New Mexico (New Mexico statutes, rules and case law are silent on corporate practice of medicine. However, a 1987 opinion from the New Mexico Attorney General provides that a corporation that is organized and controlled by non-physicians may employ physicians to provide medical services so long as such relationship is not prohibited by statute and the corporation does not exercise lay control over the physicians’ medical judgment or engage in lay exploitation of the medical profession. 87 Op. N.M. Att’y Gen. 39 (1987)); Nebraska (State Electro-Medical Inst. v. Platner, 103 N.W. 1079 (Neb. 1905)).

agreement and other contracts, which must reflect a legally compliant health care business relationship.

The FTC Rule requires disclosure relating to any restriction on sources of products or services in Item 8 of the FDD.⁹⁹ To the extent any unique insurance or bonding requirements impact the franchised business, these requirements should be disclosed in Item 8. Further, the corporate practice of medicine doctrine should be considered when drafting disclosures placing any restrictions on the medical equipment or supplies that must be used in the franchised business. As noted in III.B.1.a above, such restrictions, while common in the franchise industry, may raise issues under applicable health laws and regulations. Generally speaking, laypersons may not dictate the medical equipment and supplies medical providers must use. As such, single source product or service restrictions typically found in Item 8 may result in violation of applicable health laws and regulations.

In addition to the Item 1 disclosures regarding HIPAA, franchisors must consider whether any FDD disclosures are impacted due to HIPAA requirements (or other state data privacy issues or regulations), computer system requirements, or ownership of data obligations. If the franchisee or, in the case of a management agreement, the PC, is a “covered entity” under HIPAA, restrictions will apply relating to the ownership and sharing of certain customer or patient information. Accordingly, typical Item 11 disclosures regarding the computer system, and use and ownership of data, may need to be revised. Further, if a business associate agreement will be utilized to address HIPAA issues, appropriate disclosures regarding the required signing of the business associate agreement will need to be incorporated in the FDD, and the business associate agreement, if not included as an exhibit to the franchise agreement, should be an exhibit to the FDD, and referred to in Item 22.

To the extent the franchised business includes the provision of medical services (thus necessitating the need for a management agreement), the disclosures found in Item 15 disclosures (regarding the franchisee’s obligation to participate in the operation of the business) and Item 16 disclosures (restrictions on what the franchisee may sell) will be impacted.¹⁰⁰ Similar to the description of the franchised business found in Item 1 of the FDD, the Item 15 disclosure should describe the division of oversight and responsibilities between the franchisee and the PC. Likewise, to the extent there is a division of responsibilities relating to the products and services offered by the franchised business, such division should be detailed in Item 16 of the FDD. Also, if a management agreement is utilized it should be identified in Item 22 (and included as an exhibit to the FDD, if it is not an exhibit to the franchise agreement).

FDD Item 19, which is the disclosure of financial performance representations (or “FPRs”) does not appear to have any particular health care-specific disclosures or issues. All franchisors, no matter the industry, must have a reasonable basis for the FPR and must disclose the underlying assumptions of the FPR.¹⁰¹ Counsel should be aware of factors, if they exist, that may suggest that the underlying business from which the financial data in the FPR are drawn may not be consistent throughout the network. For example, the health care franchised businesses may operate with significantly different structures in different states; or some franchises may be owned by health care professionals and others are owned by business persons; or certain states may limit the nature of consumer/patient advertising; or some franchisees may offer services to Medicare beneficiaries and

⁹⁹16 C.F.R. § 436.5(h) (2007).

¹⁰⁰ See 16 C.F.R. § 436.5(o)-(p) (2007).

¹⁰¹16 C.F.R. § 436.5(s)(3) (2007).

receive a lower dollar-per-patient reimbursement than franchisees who choose not to provide services to Medicare beneficiaries. The franchisor needs to determine if such differences exist, and whether those differences can be explained or summarized, and still be able to present a valid, meaningful, and defensible FPR.

2. State Registration and Franchise Examiner Actions and Perspectives

The state franchise and registration laws in the fourteen so-called “registration states”¹⁰² and the administrative rules and regulations promulgated under those laws do not address the registration of health care or health care-related franchises. Except for several industries that may have statutory exceptions (e.g., beer and wine industry¹⁰³, gasoline marketing¹⁰⁴, hardware¹⁰⁵), the laws and regulations do not distinguish between one type of business or another. Consequently, any distinctions regarding the registration of health care franchises may vary depending on how different states interpret the disclosures required within the FDD. As practitioners in franchising who deal with state registrations on a regular basis know, as state examiners interpret the standards under the FDD Guidelines, sometimes inconsistencies arise between states with respect to required disclosures – in all industries. As more health care-related franchises are developed and registered, the state regulators will likely become more familiar with the industry, the different aspects of the health care and health care related businesses, and the related disclosure issues. This may drive the process to a greater degree of consistency. On the other hand, since no two health care franchises are alike, and as described above, the myriad of health laws have very different impacts depending on the nature of the business and the states of operation, individual state regulators may ask questions, or require disclosures that they have seen in other health care related FDDs, even if the particular request may not be relevant for a new or different health care business. The authors are aware of anecdotal stories in which state regulators have required more detailed disclosures regarding a health care business than other franchised businesses. In addition, at least one state has requested that a franchisor certify that the franchised businesses are legal to be operated in the state.

A concrete example of one state’s evaluation of health care franchises is California. In response to the authors’ request regarding the state’s perspective on the registration of health care franchises, a California examiner noted that the California Medical Board provides some information and guidance on its website that may assist franchise practitioners in structuring a management agreement in light of the California corporate practice of medicine.¹⁰⁶ This examiner noted that California examiners often reference this guidance when reviewing health care franchise applications. The California franchise examiner noted, however, that compliance with these guidelines and a review by the California Department of Business Oversight does not mean that the California Medical Board will agree that the franchise arrangement complies with its rules. Ultimately, franchisors still face the risk that their franchise agreement and management agreement may not withstand the scrutiny of the California Medical Board. Anecdotally, this California

¹⁰² California, Hawaii, Maryland, Illinois, Indiana, Maryland, Michigan, Minnesota, New York, North Dakota, Rhode Island, South Dakota, Utah, Virginia, Washington, and Wisconsin.

¹⁰³ See, e.g., R.I. Gen. Laws § 6-50-9.

¹⁰⁴ See, e.g., Iowa Code § 523H.1(3)(c), MINN. STAT. § 80C.91. subd. 4(f), N.Y. GEN. BUS. L. § 681(3)(b).

¹⁰⁵ See, e.g., Minn. R. & Regs. §§ 2860.7100 - 2860.7300.

¹⁰⁶ See www.mbc.ca.gov/Licensees/Corporate_Practice.aspx.

examiner noted that because of California's corporate practice of medicine doctrine and the fact that the management fee charged by the franchisee must be limited to the commensurate value of the services provided (due to California's corporate practice of medicine), the potential financial gain from a California franchisee's perspective may be limited.

As with other franchise systems, franchise counsel seeking to register a health care or health-related franchise should consider whether any federal or state disclosure and registration exemptions are available. While many franchise exemptions are not industry specific,¹⁰⁷ there may be some health care franchises that are more susceptible to securing exemptions. For example, a specialized or new surgical procedure or diagnostic service may be offered as a "franchise" to an existing medical practice. If the franchisee or medical practice is utilizing this new service, product or procedure as part of its existing business, the franchise may qualify for the "fractional franchise" exemption under the FTC Rule and several state laws¹⁰⁸ and this exemption may be a possible avenue for avoiding disclosure and/or expediting state registration.

IV. CONCLUSION

Franchising of health care businesses and health care-related businesses is expected to increase in the near- and long-term, driven by external economic factors and the efficiencies that franchising brings to many businesses. Unlike more traditional commercial or business format franchises, health care businesses are subject to many more laws and regulations governing the operation of these businesses. Health laws and regulations, at the federal and state level, affect many aspects of the franchising model. One very significant impact is that the franchised system may need to be structured so that the franchisee operates as a medical practice management company (and does not provide the medical or health care services). This is designed to honor, and not violate, corporate practice of medicine rules. These restructuring efforts, also impact the agreements and FDD. Many other health laws, not least of which are licensing and credentialing rules, fraud and abuse laws, and HIPAA, will affect the franchise agreement, other agreements such as a business associate agreement necessary for HIPAA compliance, and the daily operations of the franchisee.

The vast array of health laws and regulations, as well as the varied application of these laws depending on the nature of the business, the ownership of the franchisee, and the state in which the franchised business will be operated, require a franchise practitioner to understand the scope of these laws and their potential impact.

¹⁰⁷For example, the "large/experienced/seasoned" franchisor exemptions pertain to the net worth of the franchisor and number of outlets, see, e.g., CAL. CORP. CODE § 31101 (2012), MD.CODE REGS. § 2.2.8.10(D) (2014); R.I GEN. LAWS § 19-28.1-6(1) (2013).

¹⁰⁸16 C.F.R. §§ 436.8(2), 436.1(g) (2007) (exempting from disclosure a fractional franchise which requires: (i) the franchisee to have more than 2 years of experience in the same type of business, and (ii) the parties have a reasonable basis to believe that sales from the franchise relationship will not exceed 20% of the franchisee's total dollar volume in sales during the first year of operation); See also CAL. CORP. CODE § 31108 (2012); MINN. STAT. §§ 80C.03(f), 80C.01(Subd. 18) (2013); N.Y. Comp. Codes R. & Regs. tit. 13 § 200.10(2) (2013). *But see* FTC Informal Staff Advisory Opinion 97-7, Business Franchise Guide (CCH) ¶ 6487 (Aug. 18, 1997) in which the FTC held that a travel vaccination business franchise granted to a hospital was not sufficiently similar to the hospital's existing business, and therefore the fractional franchise exemption would not be permitted.

APPENDIX A

HEALTH CARE AND HEALTH CARE-RELATED FRANCHISES

Many types of businesses, medical practices, health care services, health-related services, and general health, nutrition and fitness businesses are often characterized as “health care.” The following, from two different franchise resources, help illustrate this wide variation in the types of businesses that are, or may be considered “health care businesses.” The first is from *Entrepreneur Magazine*, and the second is from FRANdata, the franchise research firm.

Entrepreneur Magazine, July 2014

The following is a list of health care franchises from the July 2014 *Entrepreneur Magazine* List of Franchised Businesses. The descriptions are the authors' abbreviated summary of the product or service descriptions from the Entrepreneur.com website.

<u>Company</u>	<u>Description</u>
A.T.C. Health Services	Medical staffing
Acti-Kare	Nonmedical, in-home care
Any Lab Test Now	Direct access lab testing services
Brightstar	Medical and nonmedical in-home care and medical staffing
Caring Senior Services	Nonmedical, in-home care
Comfort Keepers	Nonmedical, in-home care
Complete Nutrition	Weight loss, sports nutrition and healthy aging products
Dermacare	Medical skin care
Doctor's Express	Urgent-care services
Elements Massage	Therapeutic massage and wellness services
Family Quick Care	Retail health clinic
FirstLight HomeCare	Nonmedical in-home care
Griswold	Nonmedical, in-home care
Hallmark Homecare	Search and placement services for direct hire in-home care

<u>Company</u>	<u>Description</u>
Healthsource	Chiropractic care
Home Helpers	Nonmedical, in-home care
Home Instead	Nonmedical, in-home care
Homewatch Caregivers	Nonmedical and limited in-home health care services
Interim	Nonmedical, in-home care and medical staffing services
LaVida Massage	Massage, facials and spa services
Massage Envy	Massage, facials and other spa services
Massage Heights	Massage and facial services and sales of related products.
MassageLuxe	Massage services
Medihealth	Health and wellness screening
Medstock	Medical supplies
Miracle-Ear	Hearing testing and consultation, and hearing aid service, warranty and after-care packages
Nurse Next Door	Nonmedical and skilled in-home care
Primary Dentist	Dental services
Primary Pain Relief	Chiropractic care and rehabilitation services
RejuvaSpine	Low back and neck pain treatment
Relax the Back	Back products for sleeping or traveling and health and fitness
Right At Home	Nonmedical, in-home care
Senior Helpers	Nonmedical, in-home care
Senior's Choice	Nonmedical, in-home care
Seniors helping seniors	Nonmedical, in-home care

<u>Company</u>	<u>Description</u>
Sterling Optical	Eye exams and eyewear products and services
Synergy HomeCare	Nonmedical, in-home care
The Dentist's Choice	Dental equipment repair and servicing
The Joint	Chiropractic care
Visiting Angels	Nonmedical, in-home care
Vital Dent	Dental services

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FRANdata

FRANdata, a leading franchise research firm in Arlington, Virginia, has analyzed franchised health care businesses in a variety of contexts. FRANdata shared with the authors the following categorization or groupings of health care and health related businesses that it has utilized when reviewing industry data and FDDs:

“Health-General”: a catch-all category that includes medical practices, chiropractors, urgent care centers, vein clinics, and hypnosis centers.

“Home Health Care”: includes skilled and unskilled home care, and companion care services.

“Medical/Dental Products”: includes dental, ear, and mouth products.

“Diet and Weight Control Centers”: includes diet, weight control and nutrition centers and programs.

“Optical Products”: includes eyewear and other optical products and services.

APPENDIX B

EXAMPLES OF HEALTH CARE PROVIDERS

The following is a list of individuals and organizations, whether for profit, or not-for-profit, that are considered health care providers, and that are subject to many of the health laws and regulations discussed in Section II of the paper. Many of the existing franchised health care systems are in these fields and/or utilize these providers in the delivery of health care services or products.

Individuals

Examples of individual providers are:

- Physicians
- Dentists
- Registered nurses
- Therapists (e.g., physical therapy, occupational therapy)
- Podiatrists
- Audiologists
- Massage therapists
- Optometrists

Organizations

Examples of organizational providers are:

- Assisted living facilities
- Adult day care facilities
- Child care facilities
- Hospitals
- Hearing aid dealers
- Personal service agencies (a.k.a., home care agencies, personal care agencies, and private duty agencies)
- Home health agencies (those providing skilled nursing)
- Hospices
- Ambulatory surgical centers
- Health clinics
- Pharmacies
- Skilled nursing facilities (i.e., nursing homes)
- Laboratories

APPENDIX C

STARK LAW

The following are significant definitions under, and exceptions to, the federal Stark law.

Definitions

Definitions are important in understanding the extent of the Stark law.

- **Physician**

A physician is a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor.¹⁰⁹ A physician and the professional corporation of which he or she is a sole owner are the same for purposes of the Stark law.¹¹⁰

- **Designated Health Services**

A designated health service (“DHS”) includes any of the following services:

- clinical laboratory services,
- physical and occupational therapy and speech-language pathology services,
- radiology and certain other imaging services,
- radiation therapy services and supplies,
- durable medical equipment,
- parenteral and enteral nutrients,
- prosthetics and orthotics,
- home health services,
- outpatient prescription drugs, and
- inpatient and outpatient hospital services.¹¹¹

- **Immediate Family Member**

Immediate family member means husband or wife, birth or adoptive parent, child or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.¹¹²

- **Financial Relationship**

A financial relationship includes a physician’s (or the physician’s immediate family member’s) ownership, investment interest or compensation arrangement in the designated health

¹⁰⁹42 U.S.C. § 1395x(r) (2012).

¹¹⁰42 C.F.R. § 411.351 (2014).

¹¹¹*Id.*

¹¹²*Id.*

service entity. It includes an interest in an entity that holds an ownership or investment interest in any entity providing a designated health service.¹¹³

Financial interests are of two kinds: a direct financial relationship and an indirect financial interest, both of which are defined in the regulations.¹¹⁴

Exceptions

The Stark law contains a number of exceptions. The regulations address each of these in detail. As with the safe harbors under the anti-kickback statute, each exception requires a number of conditions to be met before the exception applies.

- **Exceptions To Ownership Arrangements**

Exceptions to ownership arrangements include the following:

- Rural providers;
- Hospitals in Puerto Rico;
- Hospital ownership; and,
- Ownership of or investment in publicly traded securities and mutual funds.¹¹⁵

- **Exceptions to Compensation Arrangements**

Exceptions to compensation arrangements include the following (there are more):

- Office space or equipment rentals;
- Bona fide employment relationships;
- Personal service arrangements;
- Remuneration unrelated to the provision of a designated health service;
- Physician recruitment;
- Isolated transactions;
- Payments by physicians;
- Charitable donations by a physician;
- Non-monetary compensation;
- Fair market value compensation;
- Indirect compensation arrangements;
- Referral services; and,
- Professional courtesy.¹¹⁶

¹¹³*Id.* § 411.354.

¹¹⁴*Id.* § 411.354(a)(2).

¹¹⁵*Id.* § 411.356.

¹¹⁶*Id.* § 411.357.

- **Exceptions to Both Ownership and Compensation Arrangements**

Exceptions to both ownership and compensation arrangements include those related to the following (there are more):

- Physician services;
- In-office ancillary services;
- Prepaid plans;
- Academic medical centers;
- Implants furnished by an ambulatory surgical center;
- Erythropoietin and other dialysis-related outpatient prescription drugs furnished in or by an end-stage renal disease facility;
- Preventive screening tests, immunizations, and vaccines;
- Eyeglasses and contacts lenses following cataract surgery;
- Intra-family referrals in rural areas.¹¹⁷

¹¹⁷ *Id.* § 411.355.

APPENDIX D

HIPAA PENTALTIES

The following is a summary of the 3-tiered system of penalties for violations of HIPAA.

Tier 1

The first tier is for violations the person did not know about and by exercising reasonable diligence would not have known about. The minimum penalty at this Tier is \$100 per violation with an annual maximum of \$25,000 for repeat violations. The maximum penalty is \$50,000 per violation with an annual maximum of \$1,500,000. Even though this Tier is strict liability, the Secretary of HHS may pursue corrective action working with the covered entity or business associate to achieve compliance in lieu of imposing penalties.

Tier 2

The second tier is for violations due to reasonable cause (i.e., with the exercise of reasonable care the breach would have been avoided) and not due to willful neglect. Violations at this Tier are subject to a minimum penalty of at least \$1,000 per violation, with an annual maximum of \$100,000 for repeat violations. The maximum penalty is \$50,000 per violation, with an annual maximum of \$1,500,000.

Tier 3

The third tier is for violations due to willful neglect. The penalty for this Tier depends on whether or not the violation is corrected.

If the violation is corrected, the minimum penalty is \$10,000 per violation, with an annual maximum of \$250,000 for repeat violations. The maximum penalty is \$50,000 per violation, with an annual maximum of \$1,500,000.

If the violation is not corrected, the minimum and maximum penalty are the same - \$50,000 per violation, with an annual maximum of \$1,500,000.

Criminal penalties are for knowingly and improperly disclosing information or obtaining information under false pretenses. The penalties are higher for actions designed to generate monetary gain. Criminal penalties range from \$50,000 and one year in prison to \$250,000 and up to 10 years in prison.

APPENDIX E

SAMPLE FRANCHISE AGREEMENT PROVISION FROM MEDICAL FRANCHISE WITH FRANCHISEE AS MANAGER

The following is a sample clause from a franchise agreement in which the franchisee will be the management company for a health care business that provide medical services and is subject to the corporate practice of medicine.

Prior to commencing operations of the Franchised Business, you must enter into a management agreement (“**Management Agreement**”) with an [physician] professional corporation (or a professional limited liability company, if permitted in the state in which the [Clinic] is located) (a “**PC**”) whereby you will provide to the PC management and administrative services and support consistent with the System and as outlined in our form of Management Agreement, a then-current copy of which is included in our in the Manual (defined in Section XX.Y), to support the PC’s [medical] care practice and its delivery of [medical] care services and related products to patients, consistent with all applicable laws and regulations. The PC shall employ and control the general [medical] physicians and the specialty medical physicians and personnel, including, for example, nurses, X-ray technicians, and medical receptionists and, together with the general practitioners, collectively, the “Affiliated Physicians” and the other [medical] care professionals who will provide the actual [medical] care services required to be delivered at and through the [Brand X Clinic]. You shall not provide any actual medical services, nor shall you supervise, direct, control or suggest to, the PC or its physicians or employees the manner in which the PC provides or may provide medical services to its patients. You acknowledge and agree that we will not provide any medical services, nor will we supervise, direct, control or suggest to, the PC or its physicians or employees the manner in which the PC provide medical services to its patients. You must use our standard form of Management Agreement; however, you may negotiate the monetary terms and, with our written consent, certain other terms of the relationship with the PC. We will not unreasonably withhold our approval to requested changes in the Management Agreement. You must obtain our written approval of the final Management Agreement prior to your execution. We must approve the PC candidate. You shall ensure that the PC offers all [medical] services in accordance with the Management Agreement and the System. If you are not able initially to find a suitable physician or physicians to create, own and staff the PC, we will attempt to help you find a suitable PC. You must have a Management Agreement in effect with a PC at all times during the operation of the Franchised Business and the term of this Agreement.

Note: The Management Agreement may be included as an exhibit to the Franchise Agreement, or may be included as an exhibit to the FDD and referred to in Item 22.

APPENDIX F

BUSINESS ASSOCIATE AGREEMENTS

The following are Business Associate Agreement terms that are required by HIPAA, along with other contract terms that are optional, but may appear in BAAs, depending upon the bargaining power or leverage of the Covered Entity or the Business Associate.

Business Associate Agreement Checklist – Required and Optional Terms

Required Terms
The following terms must appear in a Business Associate Agreement (“BAA”).
<u>Regulatory Requirements</u>
164.502(e)(1)(i): Basic Principle: A Covered Entity (“CE”) may disclose Protected Health Information (“PHI”) to a business associate (“BA”) and may allow a business associate to create, receive, maintain or transmit PHI on its behalf so long as a BAA is in place.
164.504(e)(2):
(i) Identify – By Listing or Referring to Services Agreement: Establish the permitted and required uses and disclosures of PHI by the BA.
BA Can’t do what CE Can’t do: The contract may not authorize the BA to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the CE, except for the optional management/administration and data aggregation provisions listed in the “Optional Terms” section of this checklist.
(ii) Provide that the BA will:
(A) Use/Disclose: Not use or further disclose the information other than as permitted or required by the contract or as required by law.
(B) Safeguards: Use appropriate safeguards and comply, where applicable, with the HIPAA Security Rule (Subpart C of 45 C.F.R. Part 164) with respect to Electronic PHI, to prevent use/disclosure of information other than as provided for by the BAA.
(C) Reports/Breach: Report to the CE any use or disclosure of the information not provided for by its contract, or any Security Incident, of which it becomes aware, or any Breaches of Unsecured PHI as required by 45 C.F.R. § 164.410.
(D) Subcontractors: Ensure that any subcontractors that create, receive, maintain or transmit PHI on behalf of the BA agree in writing to the same restrictions and conditions that apply to the BA with respect to such information.
(E) Access: Make available PHI in accordance with § 164.524;

(F) Amendments: Make available PHI for amendment and incorporate any amendments to PHI in accordance with §164.526;
(G) Accounting: Make available the information required to provide an accounting of disclosures in accordance with § 164.528;
Accounting: Track information needed for an accounting.
(H) Privacy Rule. To the extent BA is to carry out any of CE's obligations under the Privacy Rule, comply with the requirements of the HIPAA Privacy Rule (Subpart E of 45 C.F.R. Part 164) that apply to CE in the performance of such obligations.
(I) Records: Make its internal practices, books, and records relating to the use and disclosure of PHI received from, or created or received by the BA on behalf of, the CE available to the Secretary for purposes of determining the CE's compliance with the Privacy Rule;
(J) Return/Destroy: At termination of the contract, if feasible, return or destroy all PHI received from, or created or received by BA on behalf of, the CE that the BA still maintains in any form and retain no copies of such information or, if such return or destruction is not feasible, extend the protections of the contract to the information and limit further uses and disclosures to those purposes that make the return or destruction of the information infeasible.
Termination Provision: Authorize termination of the contract by the CE, if the CE determines that the BA has violated a material term of the contract.

Optional Terms
The following terms often appear, but are not required to be in, a BAA. Their inclusion is often a matter of negotiating power and/or leverage between the CE and BA.
Term
Mgmt/Admin of BA: The contract may permit the BA to use and disclose PHI for the proper management and administration of the BA:
USE if necessary: (A) For the proper management and administration of the BA; or (B) To carry out the legal responsibilities of the BA.
DISCLOSE if (A) The disclosure is required by law; or (B)(1) The BA obtains reasonable assurances from the person to whom the information is disclosed that it will be held confidentially and used or further disclosed only as required by law or for the purpose for which it was disclosed to the person; and (2) The person notifies the BA of any instances of which it is aware in which the confidentiality of the information has been breached.

<p>Data Aggregation: The contract may permit the BA to provide data aggregation services relating to the health care operations of the CE.</p>
<p>“Suspected Breaches”: Requirement that BA inform CE of a “suspected” Breach of Unsecured PHI and permit CE to engage in breach analysis.</p>
<p>Broader Uses/Disclosures: Any permitted uses or disclosures of PHI that are broader than those listed in the Checklist above as “Required Terms.” This may include, for example, permitting the use or disclosure of PHI for marketing, fundraising, de-identification, limited data sets or research purposes. The BA is not permitted to engage in these activities unless the CE has given BA permission to do so.</p>
<p>More Specific Restrictions: Provisions specifically addressing BA’s obligations under HIPAA with respect to marketing, fundraising, adhering to restrictions on disclosures, selling PHI, minimum necessary policies and procedures and other restrictions that apply to BA regardless of whether they are mentioned in the BAA.</p>
<p>Indemnification: Indemnification provisions (one-way or mutual).</p>
<p>Insurance: Insurance by BA to protect CE against BA’s violations.</p>
<p>Third Party Beneficiaries: Third party beneficiaries created or prohibited.</p>
<p>Assignment: Assignment prohibited or permitted.</p>
<p>Audits: Provisions obligating BA to allow CE to engage in periodic audits or inspections of the BA</p>
<p>Penalties; Injunctions: Imposition of penalties in the event of a breach or unauthorized disclosure of PHI by BA, such as liquidated damages, or provisions establishing specific performance/equitable relief for CE in event of a violation.</p>
<p>Representations: Warranties and representations that BA complies with HIPAA Security Rule and applicable provisions of Privacy Rule.</p>
<p>HITECH Amendments: Commitment by BA to comply with HITECH-based regulatory changes to HIPAA provisions in the future.</p>
<p>Workforce: Agreement by BA that its workforce will comply with applicable HIPAA provisions.</p>
<p>Mitigation: Requirement that BA mitigate any harmful effects of impermissible use/disclosure.</p>
<p>Restrictions on Subcontractors: As an alternative to the “Subcontractors” provision in the “Required Terms” section above, CEs may prohibit BAs from using subcontractors altogether or may attempt to require BA to use a particular form of Subcontractor BAA with subcontractors. CEs may prohibit BA from using subcontractors that are outside of the U.S. or not subject to jurisdiction in U.S. courts.</p>

Notifications: Provisions under which CE informs BA about: (1) CE's notice of privacy practices; (2) revocation of permission by an individual that affects BA's ability to use or disclose PHI; and (3) any restrictions on use or disclosure of PHI to which CE agrees and that affect BA's activities.

Definitions: Section of BAA setting forth defined terms; provided, however, that careful review is warranted if it appears BAA is using definitions that are different than those found in HIPAA.

Authors

JOHN GILLILAND

John Gilliland is a shareholder at The Gilliland Law Firm P.C., in Indianapolis, Indiana. His primary areas of practice are health law, labor/employment law, and HIPAA. During his 40+ years of practice, Mr. Gilliland has represented many types of providers, including hospitals, physicians, skilled nursing facilities, ambulatory surgery centers, therapists, home health agencies, and hospices, as well as assisting health care franchisors with regard health law, labor/employment and HIPAA issues.

Mr. Gilliland frequently presents programs and workshops for various local, state and national trade associations as well as for various franchisors.

He is the author of many articles for state and local associations and has written several manuals to assist health care providers in complying with legal requirements. These include: "The HIPAA Privacy and Security Compliance Resource Manual;" "Wage and Hour in Home Care;" "Home Care Employee Handbooks for Nonexempt Employees and Companions;" "Home Care Employee Handbooks for Exempt Employees;" as well as a booklet, "Labor Law for the Non-Union Agency."

Mr. Gilliland is a graduate of The Pennsylvania State University, University Park, Pennsylvania, and the Georgetown University Law Center, Washington, D.C. During law school, he was a Rotary Foundation Fellow at the Faculty of Law, Queen's University, Belfast, Northern Ireland. He was a Distinguished Military Graduate of Army ROTC and served to the rank of Captain in the U.S. Army Military Intelligence.

MARK KIRSCH

Mark Kirsch is a Principal at Gray, Plant, Mooty, Mooty & Bennett, P.A., in Washington, D.C. Mark's practice focuses on domestic and international franchising and distribution matters. He represents and counsels clients on various corporate, commercial, licensing, franchise, and business development matters. His work involves primarily transactional and regulatory matters, mergers and acquisitions, as well as counseling on dispute resolution, and mediation of franchise-related disputes.

Mark works with a wide range of clients, from large national and international chains to emerging systems, across a wide spectrum of industries including health care, restaurants and food service, various retail product and service businesses, hotels and the hospitality industry, equipment manufacturing and distribution, educational and training businesses, technology and telecommunications, and employment and personnel agencies. Mark's experience with health care related franchises includes urgent care centers, dental clinics, home health care and senior companion care services, dermatology specialists, hearing aid retailers, and weight loss centers, among others.

Mark is a frequent author and speaker at industry and bar association seminars about a variety of issues including branding, licensing, franchising, and distribution. Mark is active in the franchise industry, currently serving as Chair of the International Franchise Association's Supplier Forum, and is a member of the IFA's Board of Directors. Mark's awards and honors include

recognition in Chambers USA: America's Leading Lawyers for Business; the International Who's Who of Business Lawyers; and Best Lawyers in America. Mark received his B.A. in Economics from the University of Rochester, and his J.D. from The George Washington University.

Mark would like to thank two of his partners at Gray Plant Mooty for their valuable assistance in the preparation of this paper: Danell Caron in the franchise group, and Jesse Berg in the health care group.

MARK SIEBERT

A franchise consultant since 1985, Siebert has personally assisted over 30 Fortune 1000 companies and over 250 start-up franchisors. With offices in Chicago, Los Angeles, Dallas, Toronto, Dubai, and Jeddah, the iFranchise Group is among the world's largest franchise consulting firms. The 27 consultants at the iFranchise Group have over 500 years of experience in franchising and have worked with 98 of the top 200 franchisors listed by *Franchise Times* magazine.

Some of the healthcare and medical clients serviced by iFranchise Group consultants include AlignLife, Avada, Comfort Keepers, Delta Dental, Doctors Express, Farmicia Santa Fe, a confidential Fortune 500 Pharmaceutical company, General Nutrition Centers, a confidential major Genomics company, LA Weight Loss, Lenscrafters, Massage Envy, Medicine Shoppe, Motivation Weight Loss Centres, Pearle Vision, Senior Helpers, Sterling Optical, and Walgreens.

Siebert also serves as a Partner and Member of the Board of Directors of Franchise Dynamics, LLC, the nation's premier franchise sales outsourcing firm. Mr. Siebert has helped Franchise Dynamics grow from a start-up operation to an Inc. 5000 company with a staff of more than a dozen professionals plus support staff whose combined credentials include the sale of more than 7,000 franchises. Franchise Dynamics recently won the Illinois Excellence Award and was named one of the 100 fastest growing businesses in Chicago by Crain's Chicago Business.

In addition, Siebert is also a Partner and a Member of the Board of Directors of TopFire Media, a franchise and consumer media company that specializes in Public Relations, Search Engine Optimization, Social Media Posting, Pay-Per-Click Marketing, and Inbound Marketing.

Siebert has published about 200 articles on franchising in dozens of business and professional periodicals. He is frequently called upon as an expert witness in franchise-related cases. He was named to the *Franchise Times* list of "20 To Watch" in franchising in 2002 and the iFranchise Group was named again in 2014.

He holds a B.S. in Advertising and an M.B.A. from Northern Illinois University, and has taught undergraduate and post-graduate courses in business and in franchising at Lewis University, Loop College, and DePaul University.