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W-22: KEY CONSIDERATIONS FOR FRANCHISING IN SPECIALIZED INDUSTRIES AND SEGMENTS

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Table of Contents

Page

I. INTRODUCTION[1]

There is not much disagreement that restaurants, fitness centers, hotels, automotive repair, home maintenance, and other sectors have proven to be tailor-made for expansion through the franchise model. Indeed, these traditional business formats are usually what come to mind when most people think of franchising. While these sectors often have industry-specific regulations, they are generally compatible with franchise regulations. Other more-regulated sectors considering expansion through franchising, however, may find that their industry regulations are not as compatible with franchise regulations, and may outright conflict with them and the essence of the franchise model. In some industries and segments, the franchise model is so incompatible that utilizing exemptions and exclusions is the only way forward.

The franchise model can nevertheless provide valuable assistance within niche industries for a qualified franchisor. In some professions, franchising can offer expertise and advice on business development and operational aspects of a professional practice that the practitioner lacks time or capacity to handle. Other benefits include positioning the practitioner to handle increasing competition in the field, allowing others to tackle distracting and time-consuming administrative details, increasing name recognition, and enhancing purchasing power. Ideally, the assistance provided by franchising enables the practitioner to concentrate efforts on building a practice and servicing clients or patients.

Disadvantages surely remain, in the form of regulations within certain industries, restrictions in the ordinary controls that franchisors have over products and services, difficulty in locating qualified candidates, and in some cases, negative perceptions, both within the industry and among the general public, toward operating a "franchise" in that sector. Nevertheless, traditional benefits derived from franchising may still be realized across a range of industries, such as health care, insurance, tax and others—both professional and non-professional—notwithstanding obstacles posed by industry-specific laws and regulations, including those imposing licensure, accreditation, and certification requirements.

There is no doubt that franchisors in specialized industries include provisions in their franchise agreements that are commonplace in franchise agreements generally.[2] However, some laws that govern the above professions and sectors are subject to many nuances, are far from uniform, and unevenly enforced. They present a daunting (in some cases impossible) challenge to develop a nationwide franchise program that is consistent from state to state.

This paper explores the key considerations for franchising in specialized industries and segments, delving into the nuances that differentiate these sectors from more traditional franchising models, with particular emphasis on the business, legal, and regulatory challenges associated with developing and operating such businesses. A significant example – health care or quasi-health care businesses – are subject to limitations that include restrictions on franchise ownership, types of services offered, collection, use and protection of data, the fees paid by the franchisee to the franchisor, and the qualifications of the franchisee.

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[1] This paper represents the collective work of the authors. However, given the nature of the topic and its treatment, as well as the desire to analyze the topic in a unified paper, any particular views expressed herein do not necessarily represent the individual views of the authors.

[2] Nicole Ligouri Micklich & Lauren Lyngholm Crowe, *Professional Franchises: The More Things Change, the More They Stay the Same*, 38 FRANCHISE L.J. 563, 567-68 (2019).

II. COMPLEXITIES OF HEALTH CARE FRANCHISES IN THE CURRENT MARKETPLACE

By far the most legally complex industry for purposes of franchise regulations is the health care industry.[3] It is also primed for franchise growth, with health care spending in the United States projected to reach nearly 20 percent of the nation's gross domestic project by the year 2032.[4] As an aging and longer-living population demand more health care services, this growth may offer significant opportunities for franchisors of health care concepts.

"Health care" encompasses a wide variety of businesses and services. One end of the spectrum finds traditional health care services or practices provided by licensed doctors, dentists, pharmacists, optometrists, chiropractors, and other licensed health care professionals, as well as a burgeoning subsector of medspas, intravenous ("IV") drip and infusion centers, and related businesses typically marketed as offering cosmetic or "wellness" services, when such services may constitute medical services under state law. IV infusion therapy is a relatively new development in franchising, with its ability to deliver vitamins, minerals, and other nutrients directly into the bloodstream. IV drip and infusion centers have surged in popularity for their claimed benefits in enhancing energy levels, boosting immune function, and alleviating symptoms of various health conditions. Similarly, the appeal of "medspas" or "medi-spas," which offer a range of cosmetic procedures and rejuvenation treatments in a spa-like environment, has grown in response to increasing demand from consumers looking to address signs of aging and enhance their physical appearance.

The opposite end of the health care spectrum finds health or wellness businesses that may promote health or a healthy appearance or lifestyle, but are not themselves health care businesses (e.g., waxing and tanning salons, weight loss programs, and medical supply companies). In the current wave of proliferating health care businesses and an emphasis on wellness, even businesses tangentially related to health may be well positioned to operate with a medical service or product line as mandatory components or permissive options to the otherwise non-medical business.

Squarely in the middle are health-related services such as senior care, and health-related products such as hearing aids. Section IV of this paper will examine the legal and business considerations across this spectrum of health care business models in the current marketplace.

Historically, workable franchise models for medical services are a modern trend that has emerged within the last 20 years.[5] The medical services business model, with its own set of health laws and professional rules, created a need to develop structures that are not typical of a traditional franchised business. The corporate practice of medicine ("CPOM") doctrine, as discussed in Section III.A below, is designed to protect a health care professional's independent

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[3] For in-depth treatment of the legal issues with franchising in the health care industry, *see* John Gilliland, Mark Kirsch & Mark Siebert, *Legal Complexities of Franchising in the Health Care Industry*, ABA 37TH ANNUAL FORUM ON FRANCHISING W-16 (2014); Roger M. Quinland, *Healthcare Franchises: Just What the Doctor Ordered, or Prescription for Trouble?*, 15 Franchise Lawyer (2012); David. A Beyer & Leonard D. Vines, *A Matter of Honor: Franchising in the Professions*, ABA 26TH ANNUAL FORUM ON FRANCHISING W-9 (2003).

[4] Ctrs. for Medicare & Medicaid Servs., *National Health Expenditure Data -- NHE Fact Sheet* https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet (last mod. Jun. 12, 2024).

[5] Gilliland et al., *supra* note 3, at 3-4.

judgment. Application of this doctrine, in all but a handful of jurisdictions that follow it,[6] often means that either the franchisor must be a professional medical corporation, or the franchised business must be substantially restructured so that the health care business being franchised is not a medical, dental, or other health care practice that provides care to a patient, but rather the management and/or administration of the practice. In the latter type of franchise model, there must be clear delineation and separation of the franchisee's responsibilities and those of the medical professionals (whether practicing as individuals or under an entity formed as a professional corporation), governed by a management agreement between them.

A linchpin question of whether a health care business is sufficiently "medical" to invoke the CPOM doctrine and related health care laws can result in different outcomes under variations in state laws. Consider the example of cryotherapy. Local cryotherapy is comparable to "icing" an area of the body to reduce pain, inflammation or swelling, but in a more powerful and efficient way. It is attractive to customers with common issues such as arthritis, fibromyalgia, Muscular Dystrophy, post cancer/chemo recovery, and post-surgery recovery. Marketing of a franchised, whole-body cryotherapy center may be designed to reach customers in the pain management and sports performance markets.

Cryotherapy is not regulated by the FDA or any federal governing body. Nevertheless, both the California Medical Board and the California Department of Financial Protection and Innovation ("DFPI") take the position that if the purpose of the cryotherapy service is to provide a remedy for "an ailment, blemish, deformity, disease, disfigurement, disorder, injury, or other physical conditions" then it is within the purview of the state licensing statute that requires a California medical license for anyone who is practicing any system or mode of treating the sick or afflicted.[7] Similar examples of treatments that may not be regulated in other states have been

[6] Currently, 33 states have corporate practice of medicine regulations that are enforced to varying degrees. *See* Permit Health, *The Corporate Practice of Medicine 50-State Guide* (Nov. 21, 2023), https://www.permithealth.com/post/the-corporate-practice-of-medicine-50-state-guide; Matt Wilmot, Wes Scott & Ethan Rosenfeld, *Corporate Practice of Medicine Doctrine: Increased Enforcement on the Horizon?*, NELSON MULLINS (Jan. 17, 2023), https://www.nelsonmullins.com/insights/blogs/healthcare_essentials/enforcement/corporate-practice-of-medicine-doctrine-increased-enforcement-on-the-horizon.

[7] *See* CAL. BUS. & PROF. CODE § 2052 ("Any person who practices or attempts to practice, or who holds himself or herself out as practicing...[medicine] without having at the time of so doing a valid, unrevoked, or unsuspended certificate...is guilty of a public offense.").

found to constitute treatment requiring a medical license in California, including colon hydrotherapy,[8] microdermabrasion,[9] laser hair or tattoo removal,[10] and hypnosis.[11]

If a state medical board determines that a medical license is required to administer cryotherapy, the franchise regulators may refuse registration absent sufficient showing that the CPOM doctrine is not violated. Such state-by-state variations of whether a service is deemed "medical" can make it nearly impossible for certain types of health care business to develop a nationwide franchise program. Regardless of the geographic reach, modifications to the typical franchise model, as well as an understanding of the following health care laws, are essential to structuring a franchise program in the medical sector.

III. OVERVIEW OF HEALTH CARE LAWS

Section III of this paper provides a high-level overview of health laws and regulations that may impact franchising as a base for understanding some of the health law implications on the structuring and operation of health care and health care-related franchised businesses. Not all the health laws and regulations discussed in this section will apply to every franchised health care concept. Some apply to a franchisor and a franchisee in different ways. The authors consider five health law issues – the CPOM doctrine, fee splitting restrictions, anti-kickback laws, fraud and abuse laws, and HIPAA – to be critical for franchising.

A. Corporate Practice of Medicine

In 2022, U.S. health care spending reached $4.5 trillion (or $13,493 per person) and represented approximately 17% of our nation's gross domestic product.[12] For a large and ever-growing percentage of our population, health care can be difficult to afford. According to polling, a significant portion of American households reportedly have had problems paying for health care or skipped or postponed getting it entirely due to financial concerns.[13]

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[8] *See* 85 Ops. Cal. Atty. Gen. 134.

[9] *See* Med. Bd. of Cal., *California Medical Board Frequently Asked Questions – Cosmetic Treatments*, http://www.mbc.ca.gov/FAQs/?cat=Licensees&topic=Cosmetic%20Treatments (last visited Jun. 27, 2024) ("If the microdermabrasion is a cosmetic treatment and only affects the outermost layer of the skin or the stratum corneum, then a licensed cosmetician or esthetician may perform the treatment. If the microdermabrasion is a medical treatment, penetrating to deeper levels of the epidermis, then the treatment must be performed by a physician, or by a registered nurse or physician assistant under supervision. Treatments to remove scarring, blemishes, or wrinkles would be considered a medical treatment. Unlicensed personnel, including medical assistants, may not perform any type of microdermabrasion.").

[10] *Id.* ("Physicians may use lasers or intense pulse light devices to remove hair, spider veins, and tattoos. In addition, physician assistants and registered nurses (not licensed vocational nurses) may use lasers or intense pulse light devices to perform these procedures under a physician's supervision. Unlicensed medical assistants, licensed vocational nurses, cosmetologists, electrologists, or estheticians may not legally perform these treatments under any circumstances, nor may registered nurses or physician assistants, without supervision of a physician.")

[11] People v. Cantor, 198 Cal. App. 2d Supp. 843 (1961).

[12] Ctrs. for Medicare & Medicaid Servs., *National Health Expenditure Data – Historical*, https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/historical (last mod. Dec. 13., 2023).

[13] For example, in a 2022 Gallop poll, 38% of Americans surveyed reported they had put off medical treatment during last year due to cost. Megan Brenan, *Record High in U.S. Put Off Medical Care Due to Cost in 2022*, GALLUP (Jan. 17, 2023), https://news.gallup.com/poll/468053/record-high-put-off-medical-care-due-cost-2022.aspx. Additionally,

States, then, have an interest in making health care affordable and accessible to the greatest number of its citizens. Franchised health care systems, when properly regulated and structured, can help fill that gap by optimizing operational efficiency, profitability, and improved customer satisfaction. Franchised health care businesses, or at least those offering traditional or non-elective health care services, however, are not like other conventional franchise systems. For conventional franchise systems such as restaurants, hotels, and health and fitness clubs, it not surprising or controversial that franchisor and franchisee profitability and efficiency are guiding principles. For enterprise and for-profit health care businesses, which increasingly include franchise systems, however, it is easy to envision scenarios in which a medical provider's independent medical judgment might conflict with overall corporate profitability.

Accordingly, beginning in the 19th Century, states developed structures and regulations designed to balance the need for corporate profitability against the need to ensure the doctor-patient relationship is not (shall we say) overly infected by a commercial influence tending to prioritize profits. Known broadly as the CPOM doctrine, these laws and regulations vary by state but share the same primary focus: ensuring that medical choices are made by licensed medical professionals who have the best interests of patients in mind and who are not influenced by corporate, non-physician owners.[14]

In a general sense, CPOM laws and regulations prohibit any corporate entity from (a) providing medical or licensed health care services (as that term is broadly understood), and (b) employing physicians and other medical personnel to provide the health care services.[15] Among the states with CPOM laws and regulations, most only permit the CPOM through certain types of professional corporations or professional limited liability companies (regardless of the specific entity form, we refer to each of them in this paper as a "PC"). Additionally, most require the PC to be owned by (entirely or, in some states, a majority ownership interest) physicians licensed to practice medicine in that state.[16]

More than 30 states have CPOM restrictions.[17] Among these CPOM states, there are substantive variations in their basis, scope, and implementation. Some states have dedicated statutes and regulations governing the CPOM.[18] Others instead rely on court decisions, attorney general decisions, generalized professional corporation statutes, or various Boards of Medicine or Licensure for guidance.[19]

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according to polls conducted in 2022 and 2023 by KFF, an independent health policy organization, one in four adults reported that during in the prior 12 months they have skipped or postponed needed health care due to the cost, and six in ten uninsured adults reported going without needed care due to the cost. Lunna Lopes, Alex Montero, Marley Presiado & Liz Hamel, *Americans' Challenges with Health Care Costs*, KFF (Mar. 1, 2024), https://www.kff.org/health-costs/issue-brief/americans-challenges-with-health-care-costs.

[14] Am. Med. Ass'n, *Issue brief: Corporate Practice of Medicine* (2015), https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/premium/arc/corporate-practice-of-medicine-issue-brief_1.pdf.

[15] Permit Health, *supra* note **Error! Bookmark not defined.**.

[16] Issue brief: Corporate Practice of Medicine, supra note 14.

[17] Permit Health, *supra* note **Error! Bookmark not defined.**.

[18] In some states, violation of the CPOM prohibition is a felony punishable by fine and/or imprisonment. *See*, NY. EDUC. LAW § 6512; CAL. BUS. & PROF. CODE & PROF. CODE § 2417.5.

[19] Issue brief: Corporate practice of medicine, supra note 14.

Some states, such as California, New York, North Carolina, and Texas, are known to have comprehensive CPOM laws and regulations, and to actively enforce their restrictions. New York requires that each member of the PC be licensed to practice medicine in New York.[20] California, while still squarely in the CPOM group, offers some flexibility. California law allows physicians to incorporate as a professional medical corporation that is at least 51% owned by physician(s) licensed in the state, and up to 49% ownership by certain other types of health care licensees, such as registered nurses and physician assistants.[21] In addition, some states permit physicians and other health care providers to form multi-service or practice corporations. For example, Rhode Island allows physicians, dentists, registered nurses, podiatrists, optometrists, physician assistants, chiropractic physicians, physical therapists, psychologists, and midwives to form a PC that will combine their professions.[22] Some states, like Colorado, allow non-physicians to have a minority ownership interest as long as they have no influence over medical decisions.[23] Some states, like Kentucky, provide that nonprofit entities registered as charitable health care providers are exempt from the prohibitions against the CPOM.[24]

CPOM laws and regulations can also apply to psychologists; therapists, (chiropractors, podiatrists, dentists, orthodontists, optometrists, opticians, dietitians and med spa facilities that provide non-surgical medical-grade cosmetic procedures under the general supervision of board-certified physicians.[25] As such, the CPOM laws and regulations cast a very wide shadow when considering whether to franchise businesses that are connected to the health care industry, and how to structure them.

B. Fee Splitting Restrictions

In addition to the CPOM laws and regulations, many states have fee splitting restrictions that impact relationships between medical professionals (and in some states non-medical professionals) within a practice or group, and third parties offering services to the professional and practice groups. Broadly used, the term "fee splitting" can capture a wide range of circumstances when a medical provider shares a portion of a fee paid for health care services with another person or business. These prohibitions have been primarily aimed at situations where a health care professional, to facilitate patient referrals from other licensed or unlicensed persons, agrees to split or share a portion of the professional fee earned from treating the referred patient.[26]

The state laws and related rules regulating fee splitting, however, have evolved to apply more broadly and now prohibit business arrangements that would be lawful in ordinary fee-sharing

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[20] NY BUS CORP L § 1507 and NY LLC L § 1207(b) (2023).

[21] *See* Cal. Corp Code § 13400 *et seq*.; Cal. Bus. & Prof. Code § 2408.

[22] R.I. Gen. Laws § 7-5.1-3; *Issue brief: Corporate Practice of Medicine*, s*upra* note 14.

[23] COLO. REV. STAT. § 12-36-135(1)(d) (2018).

[24] Ky. Bd. Of Med. Op. No. 36 (1995).

[25] Permit Health, *supra* note **Error! Bookmark not defined.**.

[26] According to the American Medical Association's Code of Ethics, payment by or to a physician or health care institution solely for referral of a patient is fee splitting and is unethical. Am. Med. Ass'n, *Principles of Medical Ethics* at Opinion 11.3.4 (2016), https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/code-of-medical-ethics-chapter-11.pdf

arrangements. The fee-splitting rules are codified in statutes, and some courts have rendered decisions on their applicability and scope. Additionally, state attorneys general have opined on the subject. As is the case in many areas of evolving law, these opinions and interpretations can be very fact specific and reflect developing and sometimes shifting priorities and viewpoints on the role of business and technology providers in health care services.

State fee-splitting doctrines can be generally grouped into two broad categories: (1) prohibitions against referring patients to specific providers for health care services or related items, or from receiving patient referrals, in exchange for compensation; and (2) prohibitions against fee splitting among individuals for health care services that are not personally performed by each person sharing in the revenue.[27] State adoption and enforcement varies significantly – from none, to one or both categories. Additionally, recognizing the complexities involved in health care and the potential benefits that collaboration may offer providers and patients, many states have developed (either by legislation, opinions by medical boards and attorneys general, and case law) exceptions to their fee splitting prohibitions. One primary exception is allowing providers to form PCs, as discussed in Section III.A above. Another key exception relates to payments to third-party vendors for support services to the PC. Common support services include credentialing and licensure assistance, billing services, collection services, and other practice management support.

Arrangements in which compensation is calculated as a percentage of the revenues from the PC's medical services is prohibited by some states, either by explicit statutory prohibitions (such as New York) or in practice through regulatory opinions and case law.[28] Other states, however, may permit compensation based upon a percentage of revenue, so long as the consideration is commensurate with the value of services furnished and structured appropriately.[29] What constitutes being "structured appropriately"? The analysis can be complex and requires (a) understanding the current state guidance (which may shift over time), and (b) determining if the relevant states have identified specific types of support services that may not be part of percentage-based fees. For example, some states prohibit compensation for marketing services that is percentage-based or directly correlated to revenues from medical

[27] Ari J. Markenson & Angela Humphreys, *What Is . . . the Corporate Practice of Medicine and Fee-Splitting?: Fee-Splitting Prohibitions*, –33 THE HEALTH LAW. 3 (2021), https://www.americanbar.org/groups/health_law/publications/health_lawyer_home/2021-february/cor-pra/.

[28] New York's law explicitly states that percentage-based agreements with billing companies are impermissible. 8 NYCRR 29.1(b) ("This prohibition shall include any arrangement or agreement whereby the amount received in payment for furnishing space, facilities, equipment or personnel services used by a professional licensee constitutes a percentage of, or is otherwise dependent upon, the income or receipts of the licensee from such practice, except as otherwise provided by law ….").

[29] Illinois generally prohibits arrangements where the management fees is in direct correlation to the fees earned by the clinical practice. *See* 225 ILCS 60 22(A)(14) (2008). In *Center for Athletic Medicine Ltd. v. Independent Medical Billers of Illinois Inc.*, Ill. App. Ct., No. 1-07-1594 (May 28, 2008), a percentage-based fee arrangement between a physician group and a medical billing company was prohibited and void under the state's Medical Practice Act. However, in 2009, Section 22.2(d) of the Illinois Medical Practice Act was amended to permit a licensed provider to pay an unlicensed entity fair market value for billing, collection, or administrative preparation of claims, which may be a flat fee or based on a percentage of professional service fees billed or collected under certain conditions. Similarly, California Business & Professions Code §650(b) specifies that payment of consideration, other than for referral of patients, "which is based on a percentage of gross revenue or similar type of contractual arrangement shall not be unlawful if the consideration is commensurate with the value of the services furnished or with the fair rental value of any premises or equipment leased or provided by the recipient to the payer." In *Epic Med. Mgmt., LLC v. Paquette*, 198 Cal.Rptr.3d 28 (Cal. Ct. App. 2015), the court, relying on Section 650(b) upheld an arbitral decision to enforce a management company contract that charged percentage-based fees (50% of the revenue for office medical services, 25% of the revenue for surgical services, and 75% of the revenue of pharmaceutical related revenues).

services, while other states permit such arrangements so long as the fees represent fair market value for the services and do not involve referrals to specific providers).[30]

The second category of prohibitions and exceptions are of particular significance to franchise systems. Depending on how the franchise is structured, the franchisor and/or franchisee may be providing services to medical professionals and receiving compensation that is related, directly or indirectly, to the services rendered by these medical professionals. Additionally, it is important to note that many of the state fee-splitting restrictions are not limited to medical treatments rendered by doctors. As with the CPOM laws and regulations, many state fee-splitting restrictions apply to a broad swath of health services and medical personnel. As such, the fee-splitting restrictions are relevant not only to the traditional medical operations (such as primary care offices, urgent care centers, and dentist offices), but also to businesses that offer a combination of both medical and non-medical services, including non-medical services that are related to health conditions for which health insurance may apply.

Failure to comply with CPOM laws and regulations and related fee-splitting laws can have significant consequences, such as physician licensure action or revocation, liability of non-physician business partners for engaging in medical practice without a license, voiding of an underlying business arrangement for illegality, and recoupment of reimbursement payments by commercial or government insurers.

C. Anti-Kickback Laws

Through an amendment to the Social Security Act, in 1972 Congress enacted the first federal health care focused anti-kickback law, known as the Anti-Kickback Statute.[31] The Anti-Kickback Statute (the "AKS") prohibits health care providers from providing or receiving anything of value in exchange for referrals of patients who will receive services paid for by federal programs (e.g., Medicare or Tricare). It is designed to maintain the unbiased integrity of the decisions and actions taken by health care providers, ensuring that patient care (rather than the provider's own financial gain) is paramount. There is no minimum remuneration threshold required to trigger the AKS.[32] However, intent to induce the provider's action is an essential element.[33]

The AKS can be triggered in a number of ways, some of which are more obvious than others. Professional service rebates, excessive fees for support services, discounted fees for support services, above-market fees for office sublets, travel reimbursements, and any other item of value can form the basis for a government claim.[34]

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[30] *See* Markenson et al., *supra* note 27. The Florida Board of Medicine held that percentage-based fee arrangements are impermissible when a management services entity provides marketing or other promotional services for a health care professional. In re the Petition for Declaratory Statement of Magan L. Bakarania, M.D., 20 FALR 395 (1998), *affirmed* Phymatrix Mgmt. Co. v. Bakarania, 737 So.2d 588 (Fla. Dist. Ct.App. 1999).

[31] 42 U.S.C. § 1320a-7b(b).

[32] *See* Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 Fed. Reg. 88368, 88379 (Dec. 7, 2016) ("[T]he anti-kickback statute does not have any exceptions for items or services of nominal value.").

[33] 42 U.S.C. § 1320a-7b(b).

[34] Tycko & Zavareei Whistleblower Practice Group, *What is the Anti-Kickback Statute?* (Jan. 11, 2023), https://natlawreview.com/article/what-anti-kickback-statute.

Violating the AKS is a felony and punishable by a fine of up to $100,000 and up to 10 years imprisonment.[35] AKS violators are also subject to civil penalties up to $50,000, along with up to three times the total amount of remuneration offered, paid, solicited, or received, regardless of whether a portion of the remuneration was lawful.[36] Additionally, the Department of Health and Human Services ("HHS") Secretary may exclude AKS violators from participation in federal health care programs, and may also direct particular state agencies to exclude violators from participating in state health care programs.[37]

The AKS provides a number of exceptions. These exceptions allow providers of health care-related services to make permissible referrals by taking advantage of the "safe harbors" that are written into the AKS and except certain referral arrangements from its prohibitions. As such, health care providers often structure referral arrangements to fit within one or more of the "safe harbors" in an effort to avoid being investigated. The "safe harbors" also often provide a defense to those accused of civil or criminal violations under the AKS. By way of example, some of the "safe harbors" most often used by accused providers except the following from prosecution under the AKS: (a) referrals made as part of an employment or professional services arrangement; and (b) "payments based on valid written contracts from vendors of goods or services to authorized federal health care program purchasing agents, where the relevant providers of services disclose the amount received from each vendor…."[38]

Almost all states have enacted similar anti-bribery laws aimed at preventing corruption in the health care industry.[39] In fact, many of these laws are more onerous than the federal AKS and prohibit health care kickbacks even if the goods or services are reimbursable only by private health insurance and federal money is not involved.[40]

Although franchisors often shift the burden associated with compliance with applicable law onto their franchisees, this approach may not always be viable for health care franchisors and their actions may unwittingly expose themselves to liability. By way of example, it is common for franchisors to develop systemwide supply arrangements – designating certain vendors for products or services in exchange for a rebate on the revenue that vendor earns in connection with franchise system purchases. Imagine a health care clinic franchisor that secures an arrangement with a diagnostic lab, where the lab agrees to rebate 5% of the fees generated from patients referred to the lab by the franchise system. The rebate is a form of renumeration intended to induce the franchise brand to refer patients to the lab, thus creating a financial incentive for medical providers to refer patients for lab work solely for the rebate, rather than due to a medical necessity. These common franchise arrangements could represent a violation of applicable anti-

[35] Id.

[36] 42 U.S.C. § 1320a-7a(a).

[37] 2 U.S.C. § 1320a-7a(o)(5).

[38] *See* 42 U.S.C. § 1320a-7b(b)(3) (providing specific exceptions such as discounts or reductions, employer payments made to employees, certain amounts paid by vendors of goods, and coinsurance provisions, among others).

[39] *See*, *e.g.*, N.Y. SOC. SERV. LAW § 366-d(2) (imposing liability for receiving or making any payment for referral of goods/services reimbursable by the state health care program).

[40] *See*, *e.g.*, OHIO REV. CODE ANN. § 3999.22(B) (imposing criminal liability for receiving or making remuneration for referral of goods/services, even when reimbursable by a health care plan).

kickback laws and a direct liability for the franchisor regardless of the fact that its franchisees are engaging directly with the supplier.

D. Stark Law

Section 1877 of the Social Security Act, also known as the "Stark Law,"[41] was enacted in 1989. The AKS is similar to the Stark Law, and the two are often confused. Both sets of laws aim to regulate and penalize medical decision making that is unethically influenced by physician arrangements. However, the AKS generally covers a broader range of activities than the Stark Law and relates to referrals from any health care practitioners. The Stark Law, on the other hand, generally prohibits physicians from making "self-referrals" (i.e., referrals to physicians with whom they are immediately related or with whom they have a financial interest) to Medicare or Medicaid patients for "designated health services."[42] The Stark Law is intended to ensure that physicians are making medical referrals that are solely grounded in the patients' best interest, rather than their own gain.

The two main considerations for franchisors when reflecting upon the application of the Stark Law are (a) to which types of health care services does it apply, and (b) what constitutes a financial interest. "Financial relationships" include not only ownership or investment interests, but also other compensation arrangements (including paying a physician beyond the market value for the physician's services).[43] The law only applies to physicians who are providing certain "designated health services," such as clinical laboratory services; physical therapy, occupational therapy, and outpatient speech-language pathology services; radiology and certain other imaging services; radiation therapy services and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services.[44]

Violating the Stark Law can result in civil fines, as well as exclusion from future participation in federal health care programs such as Medicare or Medicaid.[45] Not every arrangement that fits the definitional elements of the Stark Law, however, constitutes a violation resulting in penalties. There are several exceptions, including referrals to academic medical centers, necessary in-office ancillary services (such as wheelchairs and blood glucose monitors), and physician services performed by members of the same practice group.[46]

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[41] 42 U.S.C. § 1395nn; Physician Self-Referral, U.S. Dept. of Health and Human Svcs., (Jan. 01, 2020), https://www.hhs.gov/guidance/document/physician-self-referral.

[42] Id.

[43] Id.

[44] *See* U.S. Dept. of Health and Human Svcs., Office of the Inspector General, *Fraud & Abuse Laws*, https://oig.hhs.gov/compliance/physician-education/fraud-abuse-laws (last visited Jun. 27, 2024).

[45] Id.

[46] Id.

E. Fraud and Abuse

Estimated financial losses due to health care fraud are in the tens of billions of dollars each year.[47] It is therefore no surprise that both federal and state governments have aggressively pursued and prosecuted cases of health care fraud. Common types of fraud include billing or "upcoding" for higher-priced treatment, kickbacks for referrals as discussed in Sections III.C and III.D above, performing unnecessary procedures, among a host of other dishonest practices.[48]

The federal False Claims Act prohibits knowing submission of false claims for reimbursement of health care services.[49] It also prohibits 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. Violations are subject to civil penalties in the form of treble damages plus an additional penalty of $5,500 to $11,000 for each false claim.[50]

Furthermore, as discussed above, most states have laws that generally prohibit payments made by or to a health care provider in exchange for referrals. These are similar to the AKS and the Stark Law, and penalties for submitting false claims for government reimbursement. Some state laws are more expansive and stringent than these federal laws.[51] Others apply only when a government payer is involved. It is incumbent upon the franchisor to carefully review the laws of each state in which it intends to do business to account for such state-to-state variations.

Overall, these laws can restrict the operation and marketing of franchised health care businesses. For example, there may be tension between the franchisor's established requirements for marketing and the legal limitations on the franchisee's marketing. A medical franchise that uses a web-based referral center, for example, will be limited in the manner in which the franchisee compensates the franchisor for referrals or leads. Taking vision franchises as another example, state laws vary in whether an optician may employ an optometrist. If the state allows employment of the optometrist, the franchisee optician could advertise onsite "eye exams." But if a vision franchise is owned by an optician in a state where an optometrist cannot be employed by an optician, the franchised business might only be able to advertise the retail side of the business and no optometry services. Franchisees in traditional medical service businesses (see Section IV.A below) are typically subject to compliance programs, which are sets of strict controls in place to assure accuracy of claims before submission to Medicare or other government health programs.[52]

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[47] *See* Nat'l Health Care Anti-Fraud Ass'n, *The Challenge of Health Care Fraud*, https://www.nhcaa.org/tools-insights/about-health-care-fraud/the-challenge-of-health-care-fraud/ (last visited June 25, 2024).

[48] Id.

[49] 31 U.S.C. § 3729-3733.

[50] Id.

[51] *See*, *e.g.*, CAL. BUS. & PROF. CODE § 650.01-02 (self-referral prohibition applies to persons licensed in the "healing acts" and to their family members).

[52] See Mary Beth Gettins, HIPAA Compliance Obligations Not Confined to Franchisees, 17 THE FRANCHISE LAW. (2014).

F. HIPAA/Privacy

Handling of customer data and customer privacy is an important element of any retail consumer business. In the medical sector, The Health Insurance Portability and Accountability Act of 1996 ("HIPAA")[53] and its implementing regulations and amendments[54] are best known for protecting the privacy and security of an individual's identifiable health information or "protected health information" (commonly known as "PHI"). PHI includes information relating to a person's health, health care, or payment for health care, and identifying information such as name, home address, and phone number. Through "Privacy Standards" promulgated by the HHS Office of Civil Rights, HIPAA dictates the manner in which health care providers receive, store, use, disclose, and destroy PHI. The Privacy Standards describe the purpose of disclosing such information and permitted recipients, through, among other things, the privacy rule,[55] the breach notification rule,[56] and the security rule.[57]

HIPAA applies to three kinds of "covered entities." These are (1) health care providers, (2) health care clearinghouses, and (3) health plans. Within a franchise relationship, both franchisor and franchisee could be covered entities, which means either or both must have HIPAA-compliant business associate agreements with each of their respective "business associates."[58] Section VI.B.4 below details the requirements of business associate agreements.

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[53] Pub. L. 104-191.

[54] 45 C.F.R. § 160.103 (2024). In 2009, HIPAA was amended by regulations pursuant to the Health Information Technology for Economic and Clinical Health (HITECH) Act (Div.A, Tit. XIII and Div. B, Tit. IV of Pub. L. No. 111-5).

[55] *See* 45 C.F.R. § 164.500 *et seq.* (2024). The HIPAA privacy rule addresses how a covered entity may use PHI, under what circumstances the entity may disclose PHI, individuals' rights in their own health information, and how a covered entity must notify individuals of those rights and allow them to exercise those rights. 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.

[56] *See* 45 C.F.R. § 164.400 *et seq.* (2024). HIPAA's breach notification rule requires covered health care providers to give notification to affected individuals and to the HHS Secretary of breaches of "unsecured" PHI by specified times and means. PHI is "unsecured" if it has not been secured by use of technology or methodology specified in guidance of the HHS Secretary. 45 C.F.R. § 154.402 (2013).

[57] *See* 45 C.F.R. § 164.302 *et seq.* (2024). Among other things, the HIPAA security rule 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.

[58] 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

Depending on the services a franchisor provides to its franchisees, such as billing services, processing, or converting nonstandard health information that a franchisor receives from franchisees into a standard electronic format, or vice versa, the franchisor could become a health care clearinghouse under HIPAA. This means the franchisor must have business associate agreements with any suppliers or subcontractors that create, receive, maintain, or transmit PHI on the franchisor's behalf.

IV. APPLICATION OF HEALTH CARE LAWS TO BROAD SPECTRUM OF HEALTH CARE AND WELLNESS BUSINESSES

Given the breadth of the laws and regulations described in Section III above (which is not an exhaustive discussion), it is clear that many businesses and providers of medical and other health and wellness businesses will be impacted by these health care-related laws. Given the stakes for non-compliance, each prospective franchisor should take care to analyze its operations and intended relationships as an initial step in selecting its franchise structure. Below are some threshold questions to consider while planning and developing a structure tailored to the unique features of a health care franchise system.

- What is the nature of the franchisor and what are its key contributions?
    - Is the franchisor (or its affiliates) in the medical or health care industry? Does it offer health care services to its patients or customers? Does it sell health care products that the franchisee will offer and sell to its patients or customers? Will it train or license the franchisee to perform any medical or clinical procedure or service? If so, are there any specific certifications or authorizations the franchisor will provide? Will the franchisor provide any clinical services or guidance?
    - Or will the franchisor's support services, guidance and requirements focus only on non-medical aspects of developing and operating the health care business? What are those aspects? Will those services involve any billing and collection for any medical services that must be performed by licensed health care professionals, or selecting equipment, supplies and vendors?
- Does a state in which the franchisor intends to do business consider the service to be medical? If so, can its franchisees operate profitable practice management businesses in that state?
- Who are the target franchisees and what are the key qualifications? Is the focus on physicians and other health care personnel? Or is the franchisor looking for business operators, who will then form relationships with the medical professionals who will perform the services with the ultimate patient or customer? Or is the franchisor looking

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

45 C.F.R. § 160.103 (2024).

for health care professionals who are not physicians but registered nurses, nurse practitioners, licensed vocational nurses, and other medical staff who are qualified to perform procedures that a physician need only supervise?

- Will the franchise be the sole activity of the franchisee or will this be added to the franchisee's existing business or existing health care practice?

- Will the franchisee allow (under the franchise system standards) patients or customers purchasing the health care services to pay using medical insurance, or will payment be limited to direct payment by the patient/customer and not reimbursable by insurance (often referred to as "Private Pay")? If insurance coverage is an option, will any of it be eligible for government insurance programs, such as Medicare, Medicaid, Tricare, or state equivalents?

- What types of licenses, certifications, or accreditations are required of the individuals who will render the services to the patient or customer? And are there similar requirements for the franchised facility? How widely do these requirements tend to vary by jurisdiction for the relevant services?

The factors and questions described above, which are far from exhaustive, reflect the nuances and complexities inherent in franchising traditional medical and health service operations. As such, there is no one structure that will satisfy all the potentially applicable health care laws and be best suited for all types of operations. This Section IV discusses some of the most common types of structures and franchise fee arrangements that franchise systems in the traditional health care arena have used to try to balance the competing issues.

A. Traditional Medical and Health Services

The CPOM restrictions affect both levels of the franchise system; specifically, the franchisor (assuming it is not a PC) may not control the medical staff or their delivery of medical services to patients, and a franchisee (assuming it is not a doctor or PC) may not employ the medical staff or control their delivery of medical services to the patients. As noted above, more than 30 states have CPOM laws and regulations and additional states have fee-splitting restrictions. Given that baseline condition and that most franchisors want to position their systems for nationwide or regional growth, when the services rendered to the public are traditional medical services, the franchisor often selects the practice management model as the primary structure for the franchise system.

As the name suggests, under the "practice management" model, the franchise is to develop and operate a business, as part of the franchise system, that supports – but does not render – specific health care services. The franchisor effectively separates the business aspects from the medical aspects of running an operation that delivers those health care services, and licenses the franchisee to handle the business aspects, according to the franchisor's standards, and to serve as the manager for the medical practice. The medical practices that are the public facing element of the franchise system may focus on a variety of medical services such as urgent care, primary care, chiropractic care, dermatology, dental services, and others.

The health care professionals are obviously essential to the featured medical services in these franchise systems. So, how are the medical professionals integrated into the structure? Under the practice management model, the franchisor will require the franchisee (according to the terms of the management agreement) to find a PC (or medical professionals who will form a

PC) that is duly licensed in the franchisee's state, which will conduct its medical practice at the facility the franchisee secures and establishes.

To accomplish this, the franchisee will enter into a practice management agreement with the PC, which will identify the management and support services that the franchisee will provide to the medical practice, and how the franchisee will be compensated for those services. The scope of the management and administrative services that may be typical under the management agreements is discussed further below, and while they vary between systems and the types of practices they support, the commonality is that these responsibilities do not involve the franchisee practicing medicine or controlling the medical services. The goal of this bifurcation is to create a structure where neither level of the franchise system (i.e., the franchisor setting the standards for the system, and the franchisee implementing the system) will run afoul of the CPOM restrictions by exerting control over the health care services, freeing the medical professionals to render their services as they determine to be in the best interests of patients without influence by corporate, non-physician owners.

1. Franchisee As the Practice Manager

As described above, in the practice management structure, the franchisee's functions will focus on the development of the business and facility and thereafter to the management of the overall operations and providing management and administrative support to the PC. The franchise agreement will identify the franchisee's responsibilities in operating the practice management business according to the franchisor's standards, and then in turn the management agreement will identify the support and administrative services as between the franchisee and the PC. In its role as the business developer and practice manager, the responsibilities of the franchisee may include; (a) locating a site for the facility (assuming there is a fixed location) and leasing the property; (b) building out the facility; (c) obtaining and installing the relevant medical equipment (which will be tailored to the specific health care services to be delivered by the medical staff); (d) preparing the non-medical aspects of the facility, such as waiting rooms and other amenities; (e) establishing contracts with vendors for other support and maintenance services; (f) employing and training non-medical staff; (g) assisting the PC in establishing contracts with insurance companies and third-party payors (if this will be permitted in the franchise system); (h) billing (subject to the medical professionals instructions) and collection services; and (i) in an administerial capacity, assisting the PC in tracking and maintaining applicable licensure and certification requirements.

In the authors' experience, the franchisor typically prepares a standard form of management agreement that is included as an exhibit to the franchisor's Franchise Disclosure Document ("FDD"), or at least referenced in the FDD as a component of the franchisor's operating manuals. The franchisee will be responsible for reviewing the management agreement for compliance with the health care laws (and current interpretations by the applicable professional and ethics boards, etc.) in the franchisee's state and for determining any necessary adjustments. The franchisor, through the franchise agreement, typically requires that the franchisee obtain the franchisor's approval of both the selected PC and the final terms of the management agreement, including any changes that the franchisee and the PC may have negotiated.

As the practice management functions are non-medical, the franchisee may be, and often is, owned entirely by non-medical professionals. This arrangement has the benefit of a clear demarcation that the franchisor is not employing or in a direct relationship with medical professionals, which can also simplify (but not eliminate) concerns that the royalty fees paid by the franchisee to the franchisor do not result in splitting of fees earned by the franchisee for rendering medical services. It does not, however, end the analysis of the franchisee's relationship

with the medical professionals (particularly if any of the owners are also medical professionals as discussed further below) and how the franchisee manager may be compensated for the services it provides to the PC. As discussed in Sections III.B-E above, there are federal and state laws relating to referral fees and kickbacks, as well as state laws regarding fee-splitting, all of which complicate the analysis of how the fees a franchisee must pay may be calculated and collected.

As a general matter, the management fee must, as a principal consideration, reflect the bona fide amount for the administrative services provided by the franchisee and the fair market rent for the leased office space (subject to various state limitations and interpretations). As between the franchisee and franchisor, the management fees earned by the franchisee, as well any other sources of revenue that the franchisee may generate through the franchised business for non-medical services, will be the revenues of the franchised business. On the basis that the management fee is payment for the franchisee's management services, and not for the provision of medical services, many franchisors will charge a percentage royalty fee based on the franchisee's revenues, including the franchisee's management fee.

2. Franchisee as Physician and Manager, or Licensed Provider

The discussion above illustrates the challenges of structuring to balance the CPOM, fee-splitting and other health care-related restrictions when the franchisee and the PC are entirely distinct owners. Additional considerations and nuances will apply if the franchisor wishes to offer franchises directly to medical professionals, or if one or more of the medical providers wishes to participate in the franchisee ownership and management.

These arrangements may take multiple forms and may require more significant state-to-state variation than under a practice management structure without overlap between the franchisee and PC ownership. For example, a franchisor may implement a variation in its program in which the franchisor will waive the requirement for a management agreement and practice management structure if the state where the franchisee will operate permits non-physicians to be owners in the enterprise. However, regardless of the specific structure, careful review of the arrangements will need to be conducted to ensure that the medical provider's control over medical services is not compromised and that any other necessary adjustments to the franchise fees are memorialized. A franchisor with a practice management structure may, based on state laws, be able to permit the franchisee's ownership to include medical professionals, provided that appropriate safeguards are in place.

Moreover, it's worth keeping in mind that all health-related services are not subject to the same level of restraints, and within a particular state, the laws and licensing requirements may vary significantly between different types of health-related services and products. For example, a state with a strict CPOM law for a traditional medical practice may allow pharmacies to be owned by persons without a pharmacist license, so long as all the pharmacy permits and licensing requirements, such as a qualified and license pharmacist-in-charge, are satisfied.[59]

Also, a franchisor may desire to focus on licensing directly to a PC or other medical professionals due to the franchisor's experience and qualifications in the health care field. These instances appear to arise most typically when the franchisor will license the medical franchisee to render certain services, procedures, or protocols that are unique or proprietary to the franchisor. In these situations, a central feature of the franchise is that the franchisor will provide training,

[59] For example, although Texas' CPOM laws generally prohibit non-physicians from being owners in medical practices, the requirements relating to pharmacies do not require that the owner be a licensed pharmacist (subject to meeting certain criteria and that various functions be performed by licensed pharmacists). 22 TEX. ADMIN. CODE § 281 et seq.

guidance, and in some instances certifications to the franchisee that permit the franchisee to offer those services to its patients and clientele. Given these traits, these programs are typically "add-ons" that often supplement or complement the franchisee's existing medical practices. In this respect, they may be described as "franchise light," with the franchisor's support and controls focusing on only a narrow band of activities, rather than the licensee's overall operations. Indeed, these types of arrangements may qualify for fractional franchise exemptions and exclusions, which are discussed in Section VII.C below.

3. Third-Party Payer Issues

In the health care sphere, the term "third-party payer" typically refers to an entity other than the patient that reimburses and manages heath care expenses. Third-party payers include private insurance companies, public government payers (such as Medicare, Medicaid, Tricare, and similar state bodies), and sometimes employers that pay for employee health care services. Anyone who has used medical insurance can appreciate how complicated and time-consuming issues can become when insurance and third-party payers are involved. These complications multiply for a business operating in these fields, whether as medical professionals, practice managers, franchisors, or others, each of whom will be responsible for understanding and complying with the laws relating to medical insurance coverage, reimbursements, and antifraud.

As such, one primary consideration for a franchisor is the degree to which insurance coverage and third-party payers will be part of the revenue model. At one end of the spectrum where the brand's featured services are not medically required, such as cosmetic procedures, and general fitness and wellness services and products, the services will not qualify for health insurance coverage so no analysis is required. At the opposite end of the spectrum where the focus is on routine or essential health services, a franchisor may conclude that, as a practical matter, it must structure the system to allow consumers to pay using some forms of insurance (even if only limited to private health insurance). And for many systems, there will be an analysis of the relative risks, benefits, and costs to using third-party payers.

One significant consideration is the potential application of the AKS, Stark Law, False Claims Act, and other fraud and abuse laws discussed in Section II above. As explained in more detail in those sections, these laws carry significant penalties for violations and require careful analysis of what triggers these laws and how they may curtail a variety of activities (including some purchasing arrangements, rebates, and some marketing and referral arrangements) and fee structures that are permissible in most other fields. Given these concerns, a franchisor may decide to restrict the payment options and approve only private-pay (i.e., cash out of pocket versus insurance reimbursement versus Medicare / Medicaid reimbursement) or to restrict the franchises to specific types of insurance or to private third-party payers. This approach may help reduce the compliance burdens and risks for both the franchisees and franchisor.

Other factors in the franchisor analysis include: (a) the relevant costs, including personnel time in establishing and maintaining contracts with third-party payers; (b) the degree of variation in reimbursement rates across states and regions and how those may impact franchisees differently; (c) the timeliness of payments from third-party payers and how delays may impact each business; (d) costs of potential audits; (e) patient and customer experiences; and (f) the degree to which the compensation of the franchisee as a practice manager may need to be adjusted between third-party payers. These are far from the only considerations but help illustrate that the franchisor may need to develop an approach that is tailored to its brand.

B. Elective Health Services

Unlike "traditional" medical service franchises patroned by patients seeking routine medical services, treatments provided at medspas, infusion centers, drip bars, hormone therapy, and similar clinics are unquestionably medical in nature, largely elective, and generally not considered medically necessary. While services offered by "elective" health care service providers (i.e., as anti-aging, cosmetology, or esthetic services) are marketed differently than traditional medical service businesses, they can easily cross the line into the practice of medicine and thereby trigger CPOM prohibitions, and physician licensure statutes. Accordingly, most elective health care service businesses are subject to the same structuring issues encountered in the traditional medical service model. They likewise hinge upon whether the franchisee is a medical practitioner, a non-professional manager, or administrator of a medical practice, or both.

1. Franchisee As Practice Manager

One key difference from a traditional medical service is the elective health service franchise often includes services that are both medical and non-medical in nature. Examples include cosmetic facials, infrared light therapy, stretch therapy, or compression therapy (non-medical services) offered at a medspa that also offers IV infusions, micro needling, hyperbaric oxygen therapy, blood testing or other clinical services (medical services). Although the franchisor will market the medical and non-medical elements of its services line together, it is crucial to structure the business to differentiate the two types of services.

For example, a non-PC franchisee operating a medspa business can operate in two concurrent capacities depending on whether the service being provided at a given time is medical or non-medical in nature. CPOM prohibitions generally do not prevent a layperson from providing non-medical products or services, such as operating a compression machine, and infrared light or a cryotherapy chamber, while also providing administrative services to the PC which in turn provides clinical services and products.

To honor the CPOM laws and regulations, the franchise agreement must expressly state the franchisor will not interfere with the PC's professional medical judgment in the PC's provision of medical services offered by the health care business. Outside of the PC's domain to determine the *manner* in which such medical services are rendered, however, franchisors offering an elective health service concept have an interest in limiting or restricting the *type* of services offered or treatments provided by the contracted physician. No medspa franchisor wants the PCs to cast broken bones or perform other "off-brand" medical procedures. But since contractual control will be limited by the management services agreement, franchisors must carefully screen the intended PC for assurances that the PC will stay on-brand by committing to perform only the services offered and treatments provided by the franchise. Should the PC determine that a medical service unassociated with the brand, or beyond the scope of the franchised business, is necessary, the franchisor must rely on contractual prohibitions against the franchisee or the PC using the franchisor's trademark in such situations. Sections VI.B and VI.C below address these protections in greater detail.

2. Franchisee as Both PC and Practice Manager

As discussed in Section IV.A.2 above, when the franchisee "wears both hats" of PC and practice manager, the CPOM rules and regulations in most states may bar the franchisor from exerting control over many customary facets of the franchise relationship. Areas typically reserved for franchisor approval such as site selection, facility layout, local advertising, computer software requirements, procurement of supplies, and equipment, may interfere with the physician

franchisee's professional medical judgment. A PC-franchisee will therefore have significant liberties to render medical services, hire and train medical staff, establish hours for performing medical services, among other actions. At the same time, the franchisor has a direct contractual relationship with the provider of medical services (the PC-franchisee) that is otherwise absent in the practice management model. Control over non-medical elements such as trademark appearance and usage, rights to inspect and audit the franchisee's management of the practice, systemwide funded advertising, among other hallmarks of a centralized franchise network, enable the franchisor to maintain relative brand cohesion notwithstanding some outlet-to-outlet variance from CPOM observance.

Depending on the state in which the franchised business is located, fee-splitting considerations may limit the franchisor's compensation for the license to use the franchisor's system and operation methods. A monthly flat fee for the franchisee's direct costs plus a reasonable markup, rather than a performance-based royalty, is a conservative business model for medical franchise systems to protect against fee-splitting claims, particularly where the franchisee is both a PC and practice manager. However, the authors are familiar with systems that apply a percentage royalty where the practice management franchisee and the PC agree to set the franchisee's management fee compensation at specifically defined direct costs (e.g., wages and salaries, leases, utilities, taxes, insurance, among others), plus indirect costs of certain administrative and support services that are not directly attributable to any specific activity (e.g., accounts payable, business development, education, and quality assurance) with a reasonable markup. Under either scenario, the PC-franchisee and franchisor will acknowledge in the franchise agreement that the franchisor's fee or royalty will be commensurate with the reasonable value of the services provided by the franchisor.

Faced with restrictions that inhibit the franchisor's ability to control the administration of professional medical services, coupled with limitations on the franchisor's return on investment, the franchisor may be better served by marketing the elective health service franchise to registered nurses ("RNs"), nurse practitioners ("NPs"), licensed vocational nurses ("LVNs") and other health care professionals in states where a medical doctor is not required to supervise the services offered. For various reasons, medical doctors who are trained to focus attention on working within professional practices to care for patients, as compared to establishing traditional small businesses, are not particularly likely to seek out franchise opportunities in large numbers.[60] For certain types of elective health service businesses such as IV infusion centers and drip bars, non-physicians with requisite health care experience may be better franchisee candidates. Nevertheless, properly setting the boundary between the administration of "medicine" from the administration of nutrients or vitamins (which make up the majority of IV infusion treatments), is key to establishing a franchise system in a manner that avoids falling under the embrace of restrictions that apply to traditional medical franchises.

In California, for example, IV therapy administered by an RN must be supervised by a physician or naturopath when administering medicine.[61] However, the Board of Registered Nursing interprets relevant provisions of the state nursing act to permit RNs to delegate and supervise IV therapy to certified LVNs, so long as the IV solution being administered consists of electrolytes, nutrients, vitamins, and/or blood or blood products.[62] LVNs must first complete board-

[60] *See* Gilliland et al., *supra* note 3, at 8-10 for a summary of common misconceptions about franchising within the health care industry.

[61] Cal. Bus. & Prof. Code § 2860.5.

[62] See Cal. Bus. & Prof. Code § 2860.5; 8 Cal. Code of Regs. § 2542.

approved coursework in IV therapy.[63] The takeaway for the franchise practitioner is that clearly defined boundaries between medical services that require supervision by a licensed physician, and "wellness" services that require lower level supervision by RNs can broaden the scope of potential franchisees and also allow the franchisor more control over brand standards and services offered than otherwise possible.

C. Health Care Products

Health care products are sometimes distributed through retail franchise models, such as pharmacies, optical shops, hearing aid centers, and the like. Under this model, the franchisee is generally required to purchase the inventory of products from the franchisor, its affiliates, or designees for distribution and resale at its retail locations. While these retail product-based franchise systems do not typically directly implicate the sort of CPOM, AKS, and Stark Law regulatory frameworks discussed above, their operations do implicate a host of other health care related laws (in addition to other regulations that govern retail businesses in general), that will vary greatly depending on the particular type of product offered and sold. For example, the U.S. Food & Drug Administration (the "FDA") regulates medical devices sold in the United States through the FDA's Center for Medical Devices and Radiological Health ("CDRH").[64] There are over 6,000 different classifications of regulated medical devices. Depending, in part, on the particular device classification, the CDRH will define requirements that must be met in order to offer or sell devices in the United States.[65] Once a device itself is approved for sale, the FDA may also regulate additional elements of the sale, such as device labeling and advertising.[66] The offer and sale of health care products may also require compliance with the Health Information Technology for Economic and Clinical Health Act ("HITECH"), under which health care providers, such as hearing aid retailers, must implement patient privacy and information security rules if they are or will be filing insurance claims electronically for third-party pay customers.[67] These health care product franchise models may also be subject to specialized state licensing and/or permitting requirements, such as those states that prohibit the provision of mobility-related services or home medical equipment (i.e., stair lifts or scooters) without a license.[68]

D. Home Care Services

"Home care" and "home health care" are often used together but have separate meanings. "Home health care" typically refers to medical services provided by a home health agency

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[63] 16 Cal. Code of Regs. § 2542.1.

[64] See U.S. Food & Drug Admin., Overview of Device Regulation, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation (last mod. Jan 31, 2024).

[65] *See* U.S. Food & Drug Admin., *Products and Medical Procedures*, https://www.fda.gov/medical-devices/products-and-medical-procedures (last mod. Oct. 5, 2023).

[66] See U.S. Food & Drug Admin., Device Labeling, https://www.fda.gov/medical-devices/overview-device-regulation/device-labeling (last mod. Oct. 23, 2020).

[67] See U.S. Dept. of Health & Human Servs., HITECH Act Enforcement Interim Final Rule, https://www.hhs.gov/hipaa/for-professionals/special-topics/hitech-act-enforcement-interim-final-rule/index.html (last mod. June 16, 2017).

[68] *See. e.g.,* Michigan Licensing & Regulatory Affairs, *Permitting and Licensing Requirements for Residential Stairway Chairlifts and Residential Platform Lifts*, 2015 Pub. Acts 34 & 35, amend 1976 PA 333 & 1967 PA 227, https://www.michigan.gov/lara/bureau-list/bcc/sections/elevator-unit/elevator-div-spec/permitting-and-licensing-requirements-for-residential-stairway-chairlifts-and-residential-platform-.

("HHA"). HHAs (a) are primarily engaged in providing skilled nursing services and other therapeutic services; (b) have policies established by a group of professionals (who are associated with the agency or organization), including one or more physicians and one or more registered professional nurses, to govern the services which the HHA provides; and (c) must be licensed by state or local law.[69] According to the Centers for Disease Control and Prevention ("CDC"), as of 2020, there were approximately 11,400 home health agencies in the United States, and approximately 85.5% of those were for-profit organizations.[70] HHAs are subject a wide array of health care laws, including those governing Medicare, Medicaid, and similar state laws. While there are some franchisors that include HHAs, there has been a more significant growth of "home care" franchise systems.

"Home care" (also known as "personal care") typically refers to non-medical care and personal assistance services, which are often focused on elderly individuals.[71] These services typically include care and companionship services, bathing, dressing, grooming, and personal hygiene assistance, light housekeeping, meal planning and preparation, running errands, transportation, medication reminders, and Alzheimer's and dementia care. Franchising has seen explosive growth of franchises for non-medical, in-home, and companion care services. The licensing requirements vary by state, and in some states the definition of HHA may be sufficiently broad to cover a business that will provide only the non-medical subset of services rather than the full scope of services that a HHA can be licensed to provide. Some states, such as California, require special licenses to operate in-home care businesses.[72] For some states, this is only for Medicaid providers, while in other states, every provider must be licensed. Additionally, the level of care that may be provided varies from state to state. State laws also vary as to the licensing, certification, and training requirements that each in-home worker must meet.[73]

E. Medical Services "Add-On" to Non-Medical Business

The growing demand for health care has also seen an expansion of health and wellness businesses that are non-medical in nature or minimally related to health care, such as fitness studios, day spas, waxing centers, weight loss centers, and others. Certain medical services are

[69] Ctrs. for Medicare & Medicaid Servs., *Quality, safety & oversight - Guidance for laws & regulations – Home Health Providers*, https://www.cms.gov/medicare/health-safety-standards/guidance-for-laws-regulations/home-health-agencies/home-health-providers (last mod. Sept. 6, 2023.).

[70] U.S. Ctrs. for Disease Control & Prevention, Nat'l Ctr. for Health Stats., *Biennial Overview of Post-acute and Long-term Care in the United States,* Table 1 (Oct. 19, 2023), https://www.cdc.gov/nchs/fastats/home-health-care.htm.

[71] There is not a controlling definition as to what constitutes "home care" and rather it is a term that has developed to describe care services made available to the public. See for example, Types of Home Health Care Services at https://www.hopkinsmedicine.org/health/caregiving/types-of-home-health-care-services (last visited Aug. 20, 2024), and .

[72] Effective January 1, 2016, the California Home Care Services Consumer Protection Act of 2013 has required that businesses conform to the Licensure and Certificate requirements of the Home Care Services Bureau. Accordingly, home care organizations are required to be licensed and intended to promote consumer protection for elderly and disabled individuals who hire private aides to come into their homes and provide assistance with activities of daily living. CA Health & Safety Code § 1796.10 (2023).

[73] Given the scope and variation of these requirements, it is important for a business operator to conduct a detailed analysis for the state(s) in which it will operate. For a general overview of the requirements, resources are available online. For example, PHI, *Home Health Aide Training Requirements by State*, (2016), https://www.phinational.org/advocacy/home-health-aide-training-requirements-state-2016/; PHI, *Direct Care Workers in the United States – Key Facts 2023*, (2023), https://www.phinational.org/resource/direct-care-workers-in-the-united-states-key-facts-2023/.

conducive to being added to these traditionally non-medical businesses as a permissive "add-on" options at the franchisor's discretion. For example, an emerging "hot yoga" studio brand may wish to offer its members IV vitamin drips and infusions by an onsite nurse practitioner as a post-exercise cool down and rejuvenation. If state law considers the add-on to be a medical service, and therefore subject to the rules discussed in Section III above, only the optional services should be structured according to the practice management model.

For the franchisor concerned about high added costs of offering an vitamin drip / infusion service to its non-medical yoga program, or potential liability associated with having its traditional business format franchise cross over into heavy regulation, structuring the medical service offering as an optional add-on to the core business has its advantages. For example, the optional add-on structure allows the franchisor to account for differing treatment of the IV drip / infusion service across states, control cost of legal compliance, test the concept, get a feel for whether its franchisee candidates are qualified to support a physician or nurse practitioner in the non-medical aspects of the add-on service while also overseeing operation of the core yoga service, and assess whether vitamin drip / infusion service should be a mandatory component of the franchise offering in the future.

Where the franchisor and franchisee agree that the franchised business will offer a service that is subject to the CPOM doctrine, fee splitting, and related issues, the parties may enter into an addendum to the franchise agreement that specifies modifications to the franchise agreement that enable the franchisee to offer a medical service through contracted health care providers. The terms of this kind of addendum are described in Section VI.E below.

V. CONSIDERATIONS OF OTHER SPECIALIZED OR NICHE INDUSTRIES

A. Insurance Services

The insurance sales industry is heavily regulated, primarily at the state level.[74] Insurance professionals must comply with a myriad of licensing and examination requirements, and regulations imposed by state insurance departments that govern the conduct of their businesses. Licensing is regulated at the state level and some lines of authority are subject to federal regulation. Insurance licensing requirements vary by state and by type of insurance services offered.[75] Licenses for insurance fall into two main categories, either (a) individual licenses for persons or agents providing insurance-related services in the lines of authority in which they deal, or (b) firm licenses for agencies, brokerages, and other businesses that offer insurance services, but do not own the polices themselves or hold the risk associated with the policies.[76] License requirements include pre-licensing education in the insurance lines of authority (e.g., property and casualty, life, accidental, health, and personal lines), background check and fingerprinting, passing a state examination, and continuing education.

One undergoing the development and operation of an insurance sales business franchise must bear in mind the added regulatory layer that is unique to the insurance industry. For example, in a franchised insurance agency, the franchise owner and each of its employees and agents

[74] The McCarran–Ferguson Act, 15 U.S.C. §§ 1011-1015 (1945) exempts the business of insurance from most federal regulation and gives state insurance laws preeminence over federal law.

[75] Harbor Compliance, *50-State Insurance Licensing Compliance Guide*, https://www.harborcompliance.com/insurance-license (Last updated May 1, 2017).

[76] Id.

must be licensed by the state's department of insurance to sell insurance policies.[77] In addition, a franchisee who is licensed to sell insurance must identify themselves as an agent of the franchisor with the relevant state department of insurance.[78] It follows that the required insurance licenses and certifications must be maintained in good standing with the state throughout the franchise term.

Apart from compliance with licensing requirements, brand standards from a franchise perspective may entail restrictions on supply sources. The franchisor may require that franchisees solicit the sale of insurance exclusively on the franchisor's behalf, sell policies only with carriers that the franchisor approves, and use only the premium financing companies that the franchisor approves. When structuring a franchised insurance sales business around these requirements, the threshold issue for the putative franchisor is whether the insurance broker license is held by the franchisor, or whether the franchisee will be tasked with obtaining its own broker license. Both models have their advantages and disadvantages.

The franchisor-broker model functions as follows: As the broker of record, the franchisor offers and sells insurance policies and related insurance services (e.g., policy endorsements, renewals, and reinstatements) directly through franchised agencies. The franchised agency receives payments and premiums at the point of sale, but the payment is ultimately remitted to the franchisor in full. The franchisor maintains exclusive control over separate trust accounts for the receipt of gross insurance commissions and broker fees paid by the carriers. After the franchisee binds coverage, the franchisor takes responsibility for depositing a percentage of the gross commissions and fees for the franchisee's origination of the insurance sale.

To ensure accuracy in a process that involves thousands of daily transactions, the franchisor uses producer codes to track all types of insurance transactions and the commissions and broker fees originated by the franchised agency. The franchisee is then responsible for reconciliation and verification of all commissions and fees paid, unearned commissions billed, charge-backs, and other charges received by the franchisor.

One of the franchisor's advantages in this broker model is ownership and control of the insurance products and related data. As the broker of record the franchisor owns and maintains all information received and generated from the clients acquired by the franchised agency, and the policies written by the agency. Upon expiration or termination of the franchise relationship, the franchisor may easily sever ties to the agency by removing the producer codes associated with the franchisee. The franchisor has the option of using producer codes to either establish a replacement agency to service the customers or redistribute the customers to other franchisees.

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[77] *See, e.g.*, Cal. Ins. Code § 1631 ("…a person shall not solicit, negotiate, or effect contracts of insurance, or act in any of the capacities defined in Article 1 (commencing with Section 1621) unless the person holds a valid license from the commissioner authorizing the person to act in that capacity."); Tex. Ins. Code § 4001.101 ("A person may not act as an agent unless the person holds a license issued by the department under this title."); Fla. Stat. § 626.112(1)(a) (2021) ("No person may be, act as, or advertise or hold himself or herself out to be an insurance agent, insurance adjuster, customer representative, service representative, or managing general agent unless he or she is currently licensed by the department and appointed by an appropriate appointing entity or person.").

[78] Many states have requirements for insurance agents to disclose their affiliations and the capacity in which they are acting. *See*, *e.g.*, Cal. Ins. Code § 1724.5 ("An insurance agent shall disclose, in a writing signed by the named insured, all of the following: (a) The fact that the agent is acting as an insurance agent for the insurer."); Ill. Admin. Code tit. 50, § 3120.40 (2021) ("Every insurance producer shall disclose to an applicant at the time of the initial application for insurance the name of the insurance company for which the producer is acting.")

In exchange for in-house master controls over the insurance policies and data related to the insureds, the franchisor-broker takes on administratively intensive responsibilities. In addition to collecting, tracking, and disbursing commissions for daily volumes of insurance transactions, the franchisor also takes full responsibility for marketing, carrier selection for each insurance line, and carrying the franchised agency on its errors and omissions coverage. Notwithstanding this obligation on the part of the franchisor, the franchised agency will still otherwise name the franchisor as an additional insured on its commercial liability and related policies for operation of the agency.

A concern inherent in the franchisor-broker business model is the risk of a "downstream" compensation scheme that is characteristic of misclassification or joint employer claims. Like any franchisor, a broker-model insurance franchise must maintain clear demarcation of the independent contractor relationship between the licensed agent and the brokerage (which is customary in non-franchised broker / agent relationships), as well as the agency's responsibilities with respect to hiring, firing, supervision, and discipline of agency employees. An example of this is requiring the franchisee to use agency forms for customers to sign, which state the franchisee is an independent agent procuring insurance on behalf of the franchisor.

As an alternative, the insurance franchisor may elect a more conventional franchise model, in which the franchisee must obtain the broker license, undertake its own marketing to grow the franchised business, and pay a royalty to the franchisor. The downside to this model is related to the franchisor's desire to claim ownership of the customers generated by the franchised agency. Notwithstanding provisions in the franchise agreement that provide for the franchisor's ownership of such customers, unique in the insurance agency is the fact that the franchisee is the broker of record on the policies the franchised agency sold during the franchise term. If the franchisor wishes to claim or reassign customer policies, the franchisor must inform the carriers directly and rely on the carriers to remove the franchisee as the broker of record, while also contending with a franchisee potentially claiming ownership of the customer data based on its broker license. Franchisees in the insurance business are often experienced independent operators electing to join a franchise system after already acquiring their own books of business. In this situation, franchisees are often advised to negotiate their continuing ownership of the customers that are brought into the franchise after termination of the franchised relationship.

B. Tax Return Preparation and Filing Services

Tax preparation franchises are known commodities. Major brands such as H&R Block, Jackson Hewitt Tax Service, and Liberty Tax Service have offered tax preparation services for decades. While tax preparation itself is heavily regulated by numerous local, state, and federal regulations, statutes, laws, and ordinances, the business model of a franchised tax return preparation service is otherwise quite traditional. In a typical tax preparation franchise, the franchisor shares in the direct revenues from the franchisee's offering of tax preparation services, without any fee splitting or professional judgment concerns that are typical in the health care space. The legal landscape of a tax preparation business, however, is also complex, as generally summarized below:

- Tax Laws and Tax Return Preparation Regulations. Federal and state laws, as well as U.S. Internal Revenue Service ("IRS") and state-level rules and regulations govern various aspects of a franchised tax preparation business. The U.S. Tax Code and its regulations govern eligibility, registration, and licensing of tax return preparers, the conduct of tax return preparers, and eligibility for obtaining and maintaining an

Electronic Filing Identification Number ("EFIN").[79] Franchisees in the tax preparation segment must pass "suitability" screening to obtain an EFIN.[80]

All tax preparers are required to comply with federal, state, and local rules and regulations adopted by the IRS and various other agencies. These include the requirements set forth in Treasury Department Circular 230, which establishes the rules governing those who practice before the IRS, including attorneys, certified public accountants and enrolled agents.[81] Tax preparation franchisees must also comply with IRS regulations regarding EFINs and registration requirements and rules applicable to e-file providers, such as IRS Publications 3112 (IRS e-file Application and Participation)[82] and 1345 (Handbook for Authorized IRS e-filers),[83] document retention, and privacy. Tax return preparers are also subject to accuracy-related penalties in connection with the preparation of tax returns,[84] and may be enjoined from preparing tax returns if they continually or repeatedly engage in specified misconduct.[85]

- Financial Product Regulations. The majority of state and local laws and regulations govern the facilitation and/or offering of various financial products, such as Refund Anticipation Loans ("RALs").[86] RALs are short-term interest-bearing loans provided by third-party lenders against an expected tax refund for the duration it takes the IRS and/or the state tax authority to pay the refund. The purpose of RALs are to allow taxpayers to decrease the waiting period for receiving tax refunds. They provide a revenue stream for the franchisor in the form of allowances from the lenders on each loan sold to the franchisee's customers.

  To offer RALs at a tax preparation business, the franchisee must apply for and obtain separate licenses or registrations as a loan broker or credit services organization. In addition, the franchisor will require franchisees to enter into affiliation agreements with financial vendors approved by the franchisor to offer RALs. Advertising of RALs and

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[79] See 26 U.S.C. § 6109; 26 C.F.R. §§ 1.6109-2, 301.7701-15 (2024); see also Handbook for Authorized IRS e-file Providers of Individual Income Tax Returns, I.R.S. Pub. 1345 (Rev. 3-2023).

[80] A tax preparer may not pass this screening if there is an existing dispute with the IRS or any state tax department, or if the tax preparer was assessed a tax preparer penalty, was convicted of an IRS or monetary crime, failed to file a tax return or pay taxes, or for other reasons set by the IRS.

[81] *See generally* 31 C.F.R. § 10 (2024).

[82] I.R.S. Pub. 3112 (Rev. 11-2023).

[83] I.R.S. Pub. 1345, *supra* note 79.

[84] 26 U.S.C. § 6694.

[85] *Id.* at § 7407.

[86] Currently, Arkansas, California, Colorado, Connecticut, Illinois, Louisiana, Maine, Maryland, Michigan, Minnesota, Nevada, New Jersey, New York, North Carolina, Oregon, Tennessee, Texas, Virginia, Washington and Wisconsin require disclosure of costs and terms associated with offering RALs. *See* Ark. Code Ann. § 4-114-106; Cal. Bus. & Prof. Code § 22253.1; Colo. Rev. Stat. § 5-9.5-105; Conn. Gen. Stat. § 42-480 *et seq.*; 815 Ill. Comp. Stat. 177/1 *et seq.*; La. Stat. Ann. § 9:3579.1 *et seq.*; Me. Rev. Stat. tit. 9-A, § 10-310; Md. Code Ann., Com. Law § 14-3801 *et seq.*; Mich. Comp. Laws § 445.131 *et seq.*; Minn. Stat. § 270C.4451; Nev. Rev. Stat. § 604B.010 *et seq.*; N.J. Stat. Ann. § 17:11D-1 *et seq.*; N.Y. Tax Law § 371 *et seq.*; N.C. Gen. Stat. § 53-245 *et seq.*; Or. Rev. Stat. § 673.712; Tenn. Code Ann. § 62-29-101 *et seq.*; Tex. Fin. Code Ann. § 352.001 *et seq.*; Va. Code Ann. § 6.2-2500 *et seq.*; Wash. Rev. Code § 19.265.010 *et seq.*; Wis. Stat. § 422.310.

related financial products also requires certain disclosures according to IRS and state regulations.[87]

- Due Diligence Requirements. Various IRS regulations also require tax return preparers to comply with certain due diligence requirements and to investigate factual matters in connection with the preparation of tax returns.[88] The IRS conducts audit examinations of authorized IRS e-file providers and tax return preparers by reviewing samples of prepared tax returns to ensure compliance with regulations in connection with tax return preparation activities.

- Privacy Laws. Federal and state law also requires franchisors and franchisees of tax preparation businesses to safeguard the privacy and security of customers' data, including financial information, to prevent a compromise or breach of security that would result in the unauthorized release of customer data. For instance, the Gramm-Leach-Bliley Act[89] and the Federal Trade Commission's Safeguards Rule[90] require tax preparers to, among other requirements, use physical, administrative technological means to safeguard confidential customer data, adopt and disclose customer privacy policies, and provide customers a reasonable opportunity to opt-out of having personal information disclosed to unaffiliated third parties for marketing purposes. Some states have adopted or proposed stricter opt-in requirements in connection with the use or disclosure of consumer information.[91]

- Tax Course Regulations. Tax preparation courses are a crucial marketing element for tax preparation businesses. In many states, such educational materials are subject to regulation under proprietary school laws and regulations.[92] They require tax courses to be registered and may be subject to other requirements relating to facilities, instructor qualifications, contributions to tuition guaranty funds, bonding, and advertising.

Also unique to tax return preparation franchises is their seasonal nature. "Tax Season" is generally recognized as January 1 to April 30. Certain terms in a franchise agreement are typically adjusted to ensure system stability during the tax season. For example, the franchise term may be set to expire on June 1 or July 1, after a certain quantity of tax seasons, rather than an anniversary of signing or opening the location. If a state relationship law is not applicable,

[87] Certain states require customers to have the right to rescind RALs or limit the amount of chargeable interest. *See*, *e.g.*, Minn. Stat. § 270C.4451(5) (right to rescind); N.Y. Tax Law § 372 (limiting fees); 815 Ill. Comp. Stat. 177/15 (same).

[88] For examples of IRS regulations, see 26 C.F.R. § 1.6695-2 (2024) (tax return preparer due diligence requirements for certain tax credits); 26 C.F.R. § 1.6694-1 (2024) (penalties for tax return preparers who understate a taxpayer's liability).

[89] 15 U.S.C. § 6801.

[90] 16 C.F.R. § 314.1-314.4 (2024).

[91] *See*, *e.g.*, Cal. Civ. Code § 1798.100 et seq. (California Consumer Privacy Act); Va. Code Ann. § 59.1-575 et seq. (Virginia Consumer Data Protection Act).

[92] *See* Cal. Educ. Code § 94885; N.Y. Comp. Codes R. & Regs. tit. 8, § 126.10; Fla. Stat. § 1005.31; 105 Ill. Comp. Stat. 426/20; Tex. Educ. Code § 132.055; 230 Mass. Code Regs. 15.01; Wash. Admin. Code § 490-105-040.

termination without a right to cure may also be appropriate if the franchised business closes to the public during a tax season and fails to reopen with a 48-hour period.[93]

C. Real Estate

Businesses operating real estate brokerages are subject to laws, regulations, and licensing requirements that vary on a state-by-state basis and must be taken into consideration when franchising in this industry. Many states' laws require that a licensed real estate broker actually own, manage, and/or be affiliated with the franchised brokerage. For example, to register a real estate company in Florida, at least one active Florida broker must be an officer, director, member, manager, or partner of the business entity,[94] and to apply for a license to open a real estate brokerage in Connecticut, there must be at least one licensed real estate broker who owns at least 51% of the business entity.[95] These requirements / prohibitions may limit the pool of eligible real estate brokerage franchisees. However, there are often workarounds, such as offering a qualified broker equity in a franchised business in exchange for serving in this role for the franchisee. Some real estate franchisors, in fact, have relationships with brokers who are ready to serve in this role for their franchisees.

In addition to the regulatory landscape affecting real estate brokerage franchises, there has also been significant recent litigation affecting the industry. In March 2019, a number of class action lawsuits were filed against the National Association of REALTORS® ("NAR") and various real estate brokerage franchisors, alleging that they conspired to violate Section 1 of the Sherman Act by requiring home sellers to pay buyer brokers' commissions at an inflated rate when listing a property on Multiple Listing Service ("MLS") sites.[96] The thrust of these lawsuits was based upon the NAR MLS cooperative compensation rule, under which a seller's agent was required to offer commission to the buyer's agent in order to list a property for sale on the MLS, often resulting in a real estate commission of 6% shared amongst the buyer's and seller's agents.[97] In March 2024, NAR entered into a settlement agreement in which NAR agreed to, among other things, stop requiring listing agents to offer buyer agents compensation and stop seller's agents from disclosing their commission rate on the MLS.[98] This may impact a real estate franchisor's ability

[93] Certain state franchise relationship laws deem reasonable an immediate termination of a franchise agreement without an opportunity to cure only after a longer period of closure. See, e.g., CAL. BUS. & PROF. CODE § 20021(b) ("The franchisee abandons the franchise by failing to operate the business for five consecutive days during which the franchisee is required to operate the business under the terms of the franchise, or any shorter period after which it is not unreasonable under the facts and circumstances for the franchisor to conclude that the franchisee does not intend to continue to operate the franchise, unless such failure to operate is due to fire, flood, earthquake, or other similar causes beyond the franchisee's control.").

[94] Fla. Dep't of Bus. & Pro. Regul., *What Are the Requirements To Register a Real Estate Company?*, (Nov. 15, 2010), https://myfloridalicense.custhelp.com/app/answers/detail/a_id/734/~/what-are-the-requirements-to-register-a-real-estate-company%3F.

[95] Harbor Compliance, *50-State Real Estate Broker Licensing Compliance Guide*, *Connecticut Real Estate License*, https://www.harborcompliance.com/connecticut-real-estate-license (Last updated Apr. 25, 2022).

[96] Sitzer v. Nat'l Ass'n of Realtors, 420 F. Supp. 3d 903 (W.D. Mo. 2019).

[97] Moehrl v. Nat'l Ass'n of Realtors, 492 F. Supp. 3d 768 (N.D. Ill. 2020).

[98] Nat'l Ass'n of Home Builders, *NAHB to Host Shop Talk on NAR Lawsuits*, (Apr. 23, 2024), https://www.nahb.org/blog/2024/04/nar-lawsuit-shop-talk.

to market their brand's services, particularly those low commission brands whose models are predicated upon their ability to highlight their low commission structure.

D. Legal

A developing phenomena within the legal industry, and notable for franchise practitioners, is the growing acceptability of "non-lawyer owned" law firms. For time immemorial, the legal profession has been skeptical of, if not downright hostile to, the idea of non-lawyers having any ownership interest in law firms. The profession's concerns are, in many ways, similar if not identical to those concerns giving rise to the CPOM doctrine: preserving the integrity of the attorney-client relationship from outside influence; maintaining and insulating the attorney's independent professional judgment so that the attorney may act purely in the client's best interests; and, in some cases, complying with the lawyer's duty to safeguard the client's secrets from third parties. This restriction derives from the ABA Model Rule 5.4 and similar rules adopted by state bar associations.[99] However, slowly but surely, this once unbreakable wall has begun to come down, at least in some states.

The most obvious fissure in this wall began with the rise of third-party litigation funding ("TPLF"), whereby a third party, usually a sophisticated financial operator, agrees to advance funds to subsidize a plaintiff's litigation expenses. Most often, this is in the context of plaintiff's class action lawsuits, where the expenses and upfront litigation costs can be overwhelming and out of reach for the affected class members. According to the U.S. Chamber of Commerce, TPLF is now a multi-billion-dollar industry worldwide, with an estimated $15.2 billion in commercial litigation investments in the United States alone.[100]

Critically, the funding provided is generally structured as an investment, rather than a loan, and the "collateral" is almost always the legal claim itself and not a tangible asset or property that can be repossessed. This means that in the event the claim fails, the litigation financiers are simply out of luck.[101] The nature of this relationship, then, is obviously fraught with danger as it is easy to envision any number of scenarios in which the financier's interest in getting repaid runs contrary to attorney's professional independent judgment on how to best serve the client's best interests.

Despite the dangers inherent in this sort of relationship, state bars have generally blessed them because without outside funding, many meritorious claims would never be litigated and society as a whole may suffer. Another reason is the rules of professional responsibility mandating

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[99] According to the American Bar Association ("ABA")'s Model Rule 5.4, subsection (a), in relevant part: "[A] lawyer or law firm shall not share legal fees with a nonlawyer…," while subsection (b) holds, "A lawyer shall not form a partnership with a nonlawyer if any of the activities of the partnership consist of the practice of law." MODEL RULES OF PRO. CONDUCT r. 5.4 (AM. BAR ASS'N 2024), https://www.americanbar.org/groups/professional_responsibility/publications/model_rules_of_professional_conduct/model_rules_of_professional_conduct_table_of_contents/.

[100] U.S. Chamber of Com. Inst. for Legal Reform 2024, *What You Need to Know About Third Party Litigation Funding*, (Jun. 7, 2024), https://instituteforlegalreform.com/what-you-need-to-know-about-third-party-litigation-funding/.

[101] Patrick Dempsey, *Litigation, Overview – Financing Terms,* BLOOMBERG LAW, https://www.bloomberglaw.com/external/document/X1291V78000000/litigation-overview-financing-terms (last visited, Jul. 19, 2024).

the exercise of independent professional judgment and client consent provide sufficient guardrails.[102]

Now we are seeing the next iteration – outside investors taking a direct ownership interest in firms pursuing these sorts of claims, rather than simply acting as their financiers. In fact, in 2020, Arizona eliminated its state Rule 5.4 entirely and became the first state in the nation to allow non-lawyers to own law firms.[103] Arizona replaced Rule 5.4 with a new licensing requirement for alternate business structures ("ABS") that are partially owned by non-lawyers and provide legal services. Under this licensing structure, each ABS must include at least one lawyer to serve as compliance counsel and only lawyers and other individuals licensed or certified by the Arizona Supreme Court may render the legal services.[104] According to reports, private investment money soon began flowing in, creating a legion of well-funded plaintiffs' law firms.[105]

Some additional states are either considering or implementing programs that allow non-lawyers to own law firms or to provide legal services relating to family law, landlord-tenant cases, mediations, and settlement conferences.[106] According to Bloomberg Law, at the end of 2023, ten states and the District of Columbia are considering or have implemented programs to allow non-lawyer participation in law firms, either as owners or legal advocates. As expected, however, this development is highly controversial. As with the CPOM doctrine, there will likely be a significant schism among states for many years. In fact, in 2021, Florida considered a liberalization, with the Special Committee to Improve the Delivery of Legal Services recommending certain amendments to Florida Rule 5.4 that would have, among other things, permitted minority ownership in law firms by non-lawyer firm employees and allow fee-splitting with non-lawyers. The Florida Bar Board of Governors opposed the amendments and the Florida Supreme Court agreed, allowing the longstanding Rule 5.4 to remain in effect.[107]

Notwithstanding the schism, given the trend to liberalize the practice of law in some states, can the franchising of law firms be far behind? The existing opinions and regulations governing and regulating TPLF arrangements seem to provide the skeletal outlines of a legal and analytical framework for an emerging "Corporate Practice of Law" doctrine. States have also demonstrated an interest in making litigation services affordable and accessible to the greatest number of its citizens – at least for some types of legal actions. Under the same rationale as in health care, franchised law firm systems, when properly regulated and structured, could help fill the gap by

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[102] *See e.g.*, ABA Commission on Ethics 20/20, Informational Report to the House of Delegates 23 (2012), https://www.americanbar.org/content/dam/aba/administrative/ethics_2020/20111212_ethics_20_20_alf_white_paper_final_hod_informational_report.pdf.

[103] Sam Skolnik, *Arizona First State to OK Nonlawyer Ownership of Law Firms,* BLOOMBERG LAW (Aug. 20, 2020), https://news.bloomberglaw.com/business-and-practice/arizona-first-state-to-allow-nonlawyer-co-ownership-of-law-firms.

[104] State Bar of Ariz., *Alternative Legal Services,* https://www.azbar.org/licensing-compliance/alternative-legal-services/ (last visited Aug. 26, 2024).

[105] Andy Blye, *Why One Arizona Attorney Opted for Private Equity Backing for New Law Firm*, SCOUT LAW GROUP, https://www.scoutlawgroup.com/news/why-one-arizona-attorney-opted-for-private-equity-backing-for-new-law-firm (last visited, Jul. 19, 2024).

[106] Sam Skolnik, *By the Numbers: 10 States Allowed Non-Lawyers to Offer Services*, BLOOMBERG LAW (Dec. 28, 2023), https://news.bloomberglaw.com/business-and-practice/by-the-numbers-10-states-allowed-non-lawyers-to-offer-services.

[107] In re Amends. to Rule Regulating Fla. Bar 4-5.4, 345 So. 3d 848 (Fla. 2022).

optimizing operational efficiency, profitability, and improved customer satisfaction. In short, it seems to be not a matter of if, but when, we begin to see franchised law firms within states that permit non-lawyer ownership.

VI. DRAFTING CONSIDERATIONS

The additional layers of regulation and resulting considerations that come into play for franchised businesses in specialized industries will be apparent from review of the disclosures and the applicable agreements to be disclosed. This Section VI summarizes some considerations for preparing FDDs and franchise agreements, as well as other related agreements typical of health care franchises that utilize the practice management model discussed in Section IV above.

A. Disclosures

1. Item 1

In Item 1 of the FDD, a franchisor must disclose (among other requirements), any laws or regulations specific to the industry in which the franchise business operates.[108] Many of the laws and regulations applicable to the various sectors discussed in this paper will be required to be disclosed in Item 1. For a franchisor offering a health care franchise, this disclosure may include the existence of CPOM prohibitions, federal and state anti-kickback laws, stark laws, HIPAA, the False Claims Act, the Controlled Substances Act, OSHA regulations, FDA regulations, state licensing laws, and fraud and abuse laws. The resulting relationship that the franchisee will need to form with the PC, the required management agreement they will enter into, and the responsibilities of each party thereto, will also need to be described in Item 1.

2. Item 6

Franchisors must disclose in Item 6 of the FDD "all fees that the franchisee must pay to the franchisor or its affiliates, or that the franchisor or its affiliates impose or collect in whole or in part for a third-party. . . includ[ing] any formula used to compute the fees."[109]

A health care franchisor must consider nuances of the legal framework in which it operates when drafting Item 6. For example, a franchisor's ability to collect royalties or other fees based on a percentage of gross revenues may be prohibited and/or limited by applicable law.[110] This may depend on factors such as the particular health care model, the types of services provided in the franchised business, the particular services provided by the franchisor, the customer's payment methods (i.e., cash out of pocket versus insurance reimbursement versus Medicare / Medicaid reimbursement), and the state in which the franchisor and franchisee are operating. Some franchisors only collect royalties and other fees based on the management fees paid under the management agreement, rather than all revenue earned by the PC. Other franchisors create alternative fee structures, such as a flat fee (rather than a percentage-based royalty) or a set fee, which may apply to specific services provided by the franchisor (examples include credentialing services, billing services, training, and technology systems and services) or to specific services rendered by the franchisee (examples include use of techniques, procedures, and patient or client

[108] 16 CFR § 436.5(a) (2007).

[109] 16 CFR § 436.5(f).

[110] *See* Sections III.B, IV.A.1, and IV.B.2 *infra*.

materials that the franchisor developed and licenses for use under appropriate professional supervision).

Also, given the fluid regulatory landscape affecting the health care industry, some franchisors may try to future proof their economic arrangements in a manner that would require an additional Item 6 disclosure. For example, a franchisor may include a contract provision allowing it to change the calculation of fees from time-to-time as the franchisor determines necessary to comply with applicable law. If no mutual agreement is reached with respect to such fees, the parties would have the right to terminate. The ability to modify the fees charged to a franchisee is a concept that must be disclosed in Item 6 of the FDD.[111]

3. Item 7

Franchisors must disclose in Item 7 of the FDD the franchisee's estimated initial investment, broken down by various different types of expenditures.[112] When preparing an Item 7 estimate for a health care franchise model, the franchisor and its attorney should consider the nuances of the model. For example, they should consider whether there any professional licensing that may be required of the franchisee (and what that cost may be), the costs associated with engaging attorneys and accountants to help navigate such a regulated industry, whether there is any medical equipment that must be leased from the franchisor or its affiliates, and if so, whether the leasing arrangement is prohibited by the AKS or allowed or falls within one of the 25 safe harbors available under the law, and the costs associated with employing potentially highly-skilled staff.

In addition, consideration should be given to whether the franchise is sold as a comprehensive business or rather as an add-on to an existing business. An add-on business could be a medical practice that adds an intensive care rehab facility, or that sells medical supplies to its customers, or for a medical add-on to an otherwise non-medical business (as discussed in Section IV.E above). In these situations, Item 7 should identify the costs solely related to the add-on franchise, so as not to double count costs incurred by the existing business. For example, an existing medical practice would likely already have a built out office, receptionists, nurses, vehicles, uniforms, etc., and therefore those costs would not need to be incorporated into Item 7 (unless, of course, there are marginal cost increases in the existing infrastructure to account for the add-on). Where a franchise brand offers both opportunities (i.e., to offer an add-on business from an existing business or operating the add-on business as a separate, comprehensive business), franchisors may include two separate Item 7 tables to distinguish the different costs.

4. Item 8

Item 8 requires disclosure of any restriction that the franchisor imposes on the source of products and services its franchisees must use.[113] For a health care franchise that relies on the practice management model, the Item 8 disclosure most directly impacts the medical equipment, supplies, and inventory to be used. The CPOM doctrine would, in most states, prohibit the franchisor from exercising restrictions or control over medical purchases for the franchised business, on the premise that doing so interferes with a physician's independent judgment in

[111] 16 CFR § 436.5(f).

[112] 16 CFR § 436.5(g).

[113] 16 C.F.R. § 436.5(h).

providing medical services.[114] Accordingly, Item 8 will need to disclose that the physician shall have sole discretion whether to purchase such materials from approved or designated suppliers, or that the physicians must have previously approved any equipment or supplies ordered by the franchisee for the physician's operation.

Similarly, Item 8 will need to disclose that the physician is solely responsible for procuring and maintaining professional liability insurance for errors and omissions, and all other insurance pertaining to the provision of medical services that applicable law requires. The CPOM doctrine does not otherwise modify disclosure of source restrictions on non-medical products or services provided by the franchisee's management business.

5. Item 11

Item 11 covers the various forms of assistance that the franchisor provides to its franchisees.[115] Within the franchisor's list of the types of pre-opening assistance to be provided, the FDD may describe, for example, the medical equipment the franchisor will supply, the personnel that will be trained, and the subject matter of the training. In medical franchises, disclosures of the franchisor's training program should make clear that the contracted PC will receive training in providing patient care and supervision of clinical staff, whereas an office manager or medical assistant will be trained on the front and back office operations, practice management, administration and training of additional staff and related management duties.

A unique pre-opening consideration is assessment of legal compliance in the jurisdiction in which the franchisee will operate. Presumably a health care industry franchisor has researched whether the business may be lawfully operated in a non-registration state prior to making the franchise offering, and avoided states where the business model is not legally feasible. But lest there be any doubt, a franchisor might shift to the local franchise the responsibility of confirming feasibility of the model. A disclosure of this requirement is appropriate in Item 11 (as well as Item 1) to the extent the franchisee's time to open after signing a franchise agreement is impacted by the research.[116] , Accordingly, these items may describe the franchisee's obligation to obtain written confirmation from an attorney licensed in the jurisdiction to confirm that prospective operation of the business in accordance with the franchise agreement complies with applicable CPOM rules and regulations, fee splitting, referral prohibitions and other applicable health care requirements and restrictions, as well as any proposed modifications necessary for compliance. Moreover, Item 11 should describe the franchisor's right to terminate the franchise agreement if the franchisee's attorney concludes it is not possible to operate the business in compliance with these laws, or if the franchisor determines that the modifications required to operate in compliance are impractical.

Among other things, Item 11 requires a general description in non-technical language of the computer systems (including point-of-sale ("POS") systems and electronic transaction / purchase systems) that franchisees must purchase or lease and the costs associated with those systems.[117] The computer system disclosures in Item 11 for a health care franchise must state that approvals over designated software to track customer information (e.g., contact information,

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[114] *See* Section III.A *infra*.

[115] *See* 16 C.F.R. § 436.5(k).

[116] *Id.* at § 436.5(k)(2).

[117] 16 C.F.R. § 436.5(k)(5).

purchase history, pricing, analytics), an area ordinarily reserved for the franchisor, will need be subject to the PC's approval. HIPAA will limit the non-PC franchisor's otherwise free and unfettered right to retrieve data from the franchisee's computer system. If the franchisor's proprietary or other form of computer software is required to perform a professional function, such as filing tax returns, this should also be stated in Item 11. Moreover, Item 11 should disclose that the franchisee's advertising obligations, an area ordinarily reserved for franchisor approval, are subject to the PC's approval due to federal and state laws that prohibit patient referrals, as more fully described in Section VIII.C above.

6. Item 15

Item 15 concerns the franchisee's obligation to participate in the operation of the business.[118] In some states a licensed professional franchisee may be required to own and/or supervise the franchised business. If, for example, a health care business being franchised is a management or administrative business that provides back-office services to a medical practice, Item 15 needs to describe the division of oversight and responsibility between the franchisee and the PC.

7. Item 16

Item 16 requires the franchisor to describe any restrictions that it places on the goods or services that a franchisee may sell or the customers to whom it may offer and sell those goods and services.[119] In the highly regulated industries, particularly those where the franchisor's right to dictate standards to professionals may come into play, this item presents unique considerations. The health care industry is a key example.

As discussed in Section IV.A above, to facilitate compliance with broad CPOM and other health care restrictions, many franchisors will implement a practice management structure. In these circumstances, Item 16 should describe the division between the franchisee's non-clinical role as the practice manager, and the responsibilities of the PC relating to health care services and professional staff. Additionally, to make clear the limitations on the franchisee with respect to the CPOM laws and regulations, it is recommended that Item 16 affirmatively note that the franchisee may neither render any medical services, nor supervise, direct, control, or suggest, to the PC or its physicians or employees the manner in which the PC provide medical or urgent care services to its patients.

Alternatively, if the franchisor uses a structure in which the franchisee may serve as the medical provider, either as the base structure of the franchise system or as an approved variation in states with less restrictive laws, then Item 16 should reflect the scope of the franchisee's rights and responsibilities, as well as the applicable limitations on the franchisor's role in setting standards that relate to the health care services.

8. Item 19

"How much money can I make?" Item 19 is the opportunity for a franchisor to address this common and important question from prospective franchisees. Indeed, if a franchisor subject to the FTC Franchise Rule and state franchise laws wishes to provide financial performance representations ("FPRs") to a prospective franchisee, it must do so in the context of Item 19 of

[118] 16 C.F.R. § 436.5(o).

[119] 16 C.F.R. § 436.5(p).

the FDD.[120] To make an FPR in Item 19, a franchisor must have a reasonable basis at the time it is made and must describe its factual basis and the material assumptions underlying its preparation and presentation.[121] On initial consideration, it seems therefore that Item 19 and FPRs do not present any unusual issues for a franchisor of highly regulated industries, such as health care. A deeper look, however, reveals that there are both special factors to consider and potential opportunities to tailor FPRs to the metrics most relevant to the regulated businesses. Examples of factors and issues to consider include:

- What business structure(s) applies to both the relationship between the franchisor and franchisee, and at the franchisee level with the regulated providers? Is a practice management model used in some or all states? Are medical professionals owners of the franchised business and if so, does that have a material impact on the revenues that may be collected by the franchisee?

- What are the revenue streams of the franchisee? If a practice management model is used, how are the franchisee's management fees calculated and how do they vary between states (based on CPOM, fee-splitting, and other restrictions)? Does the franchisee collect revenues from other non-regulated products or services?

- At the service and product level, what are the sources of payments? For example, will patients and customers typically pay for services through private or government insurance programs, or privately pay out of pocket? For services and products covered by private or government insurance, is there a significant variation between the reimbursement rates across the system for the core services rendered? If payment is through insurance programs, does this impact the collection rates and the timing of payment? If the franchisor is able to contract directly with the PC or medical professional, are franchisee revenues measured on their billings or collections?

- Are many franchisees conversion franchisees or existing providers that are adding the franchise component to their existing practice or business? If so, how may this affect the base of potential customers and franchisees?

- Are there restrictions in particular states that may impact the franchisee performance or costs that should be noted? For example, some states have restrictions relating to advertising to potential patients and how service providers (which may include franchisees and franchisors) may be compensated for advertising services.

- If the franchisor wishes to report any costs or gross profit disclosures, how do the relevant industry regulations affect the franchisee level costs, and do these vary significantly by state?

In addition to these considerations, features of health care field offer the franchisor an opportunity tailor its FPRs to reflect financial metrics that are meaningful to potential participants beyond overall revenue. In the franchise system, are there specific drivers of the services and revenue? In some health care systems, the number of available doctors, nurses, technicians,

[120] 16 C.F.R. § 436.9(c)

[121] 16 C.F.R. § 436.5(s)(3).

estheticians, and care givers may be a driving factor. In others, perhaps the number of treatment rooms or equipment (for example, lasers for cosmetic procedures) may be important factors. Once these factors are analyzed, and provided there is sufficient reliable data, the franchisor may be able to deliver FPRs that are customized based on those performance levers.

9. Item 22

In highly regulated fields, like health care, the franchisor may incorporate additional agreements and forms as part of its standard franchise documents. These may include a template form of management agreement for practice management structures, business associates agreements to address HIPAA issues, clinical support agreements with certain providers, billing management agreements, and the like. To the extent that these types of agreements and tools are implemented in the franchise system, they should be identified in Item 22 and included as an exhibit to the FDD or franchise agreement.[122]

B. Franchise Agreement

Due to the additional regulatory overlay in specialized industries, particularly in the health care industries and other professional fields, franchises in these fields tend to have a common set of issues that need to be addressed in the franchise agreement and ancillary documents. This Section VI.B focuses on health care driven terms, but the issues underlying these terms will also be relevant to other fields where the consumer must rely upon specialized knowledge or training of the franchisee and its personnel.

1. Disclaimer of Control Over Medical Services and Related Franchisee Representations

A cornerstone of franchising is that the franchisor will establish brand standards that, when observed, allow customers to enjoy consistent experiences regardless of which franchise or company-owned operation they encounter. Franchise agreements, accordingly, reflect broad rights of the franchisor to establish those standards and the process by which franchises must operate to meet those brands standards. For health care industry franchises, however, it is imperative to distinguish the franchisor's rights to control ordinary operating standards from controls that would impact the professional judgment of the medical service providers. While the specifics will vary based on the types of health care services, the franchise structure selected, and whether the franchisor is licensing specific medical products or services, the franchise agreements at issue will typically be modified to include the following terms and representations.[123]

- A clear description of the scope of the franchise system (for example, in practice management models, it will describe how the system enables the franchised business to support health care providers in their practices or in providing the select medical services), and that the franchisor will not provide any medical or health care services, nor will the franchisor supervise, direct, control, or suggest to, the PC or its medical professionals the manner in which they provide medical services to patients.

[122] 16 C.F.R. § 436.5(w).

[123] To the extent that franchise program is structured so that franchisee is a PC or the franchisor is directly licensing the franchisee to provide a specific licensed health care service, these terms may not apply or will need to be adjusted accordingly.

- Restrictions and representations that the franchisee will not provide any actual medical services, and will not supervise, direct, control, or suggest to, the PC or its medical professionals the manner in which they provide medical care services to patients.

- The PC or physician will be the only party to employ and control the physicians and the specialty medical physicians and personnel (which may include nurses, physician assistants, medical receptionists, and other health care professionals), who will provide the actual medical services to be delivered by the medical practice. Additionally, the franchisee will not interfere with the PC's responsibility as to the compensation, supervision, scheduling, evaluation, and discipline of the medical professionals.

- The PC and each doctor and health care provider retains full control and independent judgment regarding all medical, pharmaceutical, professional, and ethical aspects of their medical practices and provision of medical services.

In addition to these terms that concern overall structuring of the franchised business and allocation of the parties' respective roles, terms often need to be added or adapted. For example:

- Descriptions of the equipment and assets that the franchisor designates or recommends for use should reflect the intention that these are not to interfere with the judgment of the medical professionals and may be subject to the approval of the medical professionals for medical equipment and supplies.

- In the event the PC or medical professional determines there is a conflict between a brand standard or franchisor requirement and their judgment as to the performance of medical services and operations of the medical practice, the franchisee may deviate from the mandatory specifications and procedures in the specific instances as determined necessary by the medical professional. Additionally, in such instances, the franchisee will submit the medical professional's conclusions to the franchisor for further evaluation and resolution.

- Hours of operation is another area where franchisors typically exert some control, at least to set certain minimum, daily operational hours. In connection with medical services, the franchise agreement will need to reflect that the PC will be solely responsible for determining how many patients a physician or other medical professional will see in a given period of time or how many hours a physician or other medical professional will work.

- Franchise agreement terms regarding technology systems, privacy, and data also present unique issues. As discussed in Sections III.F and VI.A.9 above, depending on the scope of the business and the franchisee's support functions, the franchisee may be subject to HIPAA and required to sign a business associate agreement, typically in the form the franchisor requires. Additionally, under relevant state health care laws and ethics opinions, ownership and control of medical records may be an indicium of control over medical services, therefore any language should be carefully reviewed

and adjusted to avoid any unintentional overreach by the franchisor or the franchisee.[124]

Finally, considering the highly regulated nature of health care services and the web of legal restrictions may continue to evolve, a franchisor should consider how it will handle variations and changes in the regulatory landscape. State variations are likely to be resolved easily. For example, the franchisor can prepare and implement state-specific amendments to the franchise agreement and other agreements, such as management and billing service agreements to conform the practice to the state law.

Changing laws, however, present trickier issues, particularly for systems where the franchisor's relationship is directly with medical professionals and where the compensation between the franchisor and franchisee is directly tied to receipts from the health care services. Changes may arise from statutes, applicable case law, regulations or interpretations, the adoption of new federal or state legislation, and changes in government and other third-party reimbursement systems. These may have significant impacts on the permissible roles of the parties and how to structure compensation, and could even render the franchise agreement as originally written unlawful. There is no perfect solution to this potential dilemma, but the franchisor should consider including in the franchise agreement terms to address the process and parameters under which the parties will negotiate and seek to resolve such issues.

2. Insurance and Indemnification

The importance of a well drafted and robust franchise agreement indemnification provision cannot be understated. The indemnification provision affirms the risk allocation upon which the economic model of franchising is based (i.e., the franchisor earns a small percentage of the franchisee's operating revenue in exchange for a small amount of legal risk associated with the franchisee's operations, whereas the franchisee is an independent business owner, who accordingly bears the lion's share of the legal risk associated with its operations and retains a commensurate lion's share of its own revenue). This is true of all franchise business models, but is of particular importance in heavily regulated industries such as health care, where the potential liabilities can be significant and complex.

In such industries, franchisors should do more than simply requiring the franchisee to indemnify the franchisor for all costs, damages, and liabilities related to or arising out of the franchisee's ownership or operation of the franchised business and/or the acts, errors, or omissions of its representatives. Health care franchisors, for example, would be wise to more precisely articulate indemnified claims that may arise – such as those relating to the rendering of services or patient care, the marketing of the health care services, and the violations of health care laws and licensing requirements. Further, where a management agreement is in place, the management agreement should be similarly broad, and provide for the indemnification of the franchisor for claims relating to the PC (and/or its staff), claims arising from services provided by the PC or its staff, and claims arising from or relating to the management agreement or the relationship between (a) the PC and the franchisee, (b) the PC and the PC's staff, and (c) the PC's staff and the franchisee.

Importantly, an indemnity provision is only as good as the financial assets available to support a claim. For that reason, the franchisor should mandate the franchisee maintain minimum

[124] *E.g.,* Cal. Med. Bd., *Physicians and Surgeons,* https://www.mbc.ca.gov/Licensing/Physicians-and-Surgeons/Practice-Information/, (last visited Aug. 30, 2024).

insurance requirements which have been vetted by the franchisor's insurance broker. These may include medical malpractice insurance against claims for bodily and personal injury and death (which should also cover any medical professional or staff working at the business), any insurance required as a condition to licensure, cyber liability coverage, medical director professional liability insurance, and any and all other indemnified claims. These policies should also expressly name the franchisor and its affiliates as additional insureds and include tail coverage to extend past a particular PC or business associate's departure from the franchise.

3. Transfers, Defaults, Termination

Transfers of health care businesses are complex transactions that may take many months due to required government approvals. For example, certificate of need requirements and Medicare, Medicaid or other health care reimbursement programs may require prior notice or approval of a change of ownership of a provider participating in a reimbursement program. Approval may entail criminal background checks, and limitations on billing until the change in ownership (known in health care parlance as "CHOW") is processed by the government agency involved. Health care franchisors will typically have language in their franchise agreement's transfer provisions requiring that all applicable federal reimbursement program transfer requirements and notifications be satisfied prior to the franchisor's consent to the transfer. Further, for health care franchises applying the practice management model that do not participate in federal reimbursement programs, the CPOM doctrine requires that the medical professional have approval rights for a proposed transfer of the management service provider to the transferee.

Health care franchisors should account for events unique to the practice management model that amount to cause for ending the franchise relationship. For example, a ground for default and/or termination is failure of the practice manager to service the medical professional in accordance with applicable law. Another example is the practice manager franchisee's failure to replace a departing medical professional within a certain time period.

Upon termination the franchisor may desire to take possession of patient medical records. HIPAA Privacy Standards authorize a "health care provider" to transfer its PHI to a purchaser / transferee upon the sale or transfer of the health care provider's practice, provided that after the transfer the purchaser / transferee will be bound by the Privacy Standards (i.e., the purchaser is a health care provider, health clearinghouse, or health plan).[125] The franchisor therefore will be free to transfer the patient records to another health care provider upon termination, but the Privacy Standards may prohibit the franchisor from taking direct possession of such records upon termination of the franchise.

4. Non-competition

Non-competition covenants with a legitimate basis and narrowly tailored in terms of temporal and geographic scope have historically been upheld. However, the tide has begun to turn. In April 2024, the Federal Trade Commission ("FTC") issued a nationwide ban on competitive restrictions.[126] With respect to almost all workers, it is per se an "unfair method of competition" for an employer to: (1) enter into or attempt to enter into a non-compete clause; (2) enforce or attempt to enforce a non-compete clause; or (3) represent that a worker is subject to a non-compete

[125] 45 C.F.R. § 164.502(a)(3) (2024)**;** ***see also*** Gilliland, supra, note 3, at 28-29.

[126] FTC Final Non-Compete Clause Rule, 16 C.F.R. § 910.6 (2024).

clause.[127] The ban includes an express carve out for the franchisor-franchisee relationship, but would nevertheless have a significant impact on the franchise model (e.g., by limiting the franchisee from imposing non-compete restrictions on its employees, even if they have access to the franchisor's confidential and trade secret information). While the ban is scheduled to take effect in September 2024, numerous stakeholders have already begun filing lawsuits and many experts believe that the ban may ultimately fail. In fact, on August 20, 2024, the United States District Court for the Northern District of Texas issued an order setting aside the FTC's ban on employee noncompetes on a nationwide basis in *Ryan v. The Federal Trade Commission*.[128]

A number of states have also begun proposing their own legislation to ban or restrict the use of non-competes. Some generally restrict the use of any non-compete in the state, and others only apply to specific industries. As of June 2024, at least 14 states had introduced legislation specifically addressing the use of non-competes in the medical field.[129] These bills range from prohibiting medical residents from signing non-competes (Arizona), to limiting a physician who leaves a hospital to go into independent practice from continuing to see the physician's patients (Colorado), to declaring void any non-compete that restricts the right of a physician to practice medicine (Georgia).[130]

The legal landscape governing the use of non-competes will likely stay in flux and vary on state and federal levels going forward. While some courts may modify or limit an unenforceable contract provision so that the remainder of the agreement is enforceable, others do not. As such, franchisors must weave a delicate balance between actively protecting their trade secret information and not risking the enforceability of their entire contract and/or confidentiality and non-competition agreements. To the extent possible, agreements should be future proofed to provide franchisors with maximum flexibility. To accomplish this task, franchisors should consider including provisions in the franchise agreement (as well as and other related agreement that include such a restriction) addressing the following:

- The ability of future courts to blue pencil the non-compete provision in order to fall within permissible legal limits.

- The ability of the franchisor to unilaterally decrease the period of time or geographic scope of the non-competition covenant or otherwise modify it in a way as may be necessary to comply with applicable law.

- The franchisee's sole obligation to ensure that any form of confidentiality and non-compete agreement required of its managers or other employees complies with applicable state, federal and local law.

- Franchisors may also want to consider creating separate standalone confidentiality and non-competition agreements, such that in the event the non-competition agreement was declared unenforceable and a court would not blue pencil the

[127] FTC Final Non-Compete Clause Rule, 16 C.F.R. § 910.2 (2024).

[128] Ryan LLC v. Fed. Trade Comm'n, No. 3:24-CV-00986-E, 2024 WL 3297524 (N.D. Tex. July 3, 2024).

[129] Economic Innovation Group, *State Noncompete Law Tracker*, https://eig.org/state-noncompete-map/ (last updated Aug. 21, 2024).

[130] Id.

agreement, the franchisor would not also lose the benefit of the confidentiality protections.

One element of the use of restrictive covenants in the health care space, however, is different than in most other industries. That is the requirement that health care professionals put patient care above all else. With this paramount aim in mind, the authors recommend that any non-competition prohibition imposed on a franchisee / PC include a carve out that would enable the franchisee / PC to divert or attempt to divert any client or potential client to any other business (including a competitor) as they deem necessary in their professional and medical judgement. In addition, where the health care franchise model allows an ancillary add-on business (such as a medical office that adds on a franchised rehabilitation center, or a physical therapy office that adds on chiropractic franchise element), a franchisor may want to consider tailoring the definition of a competitive business to avoid preventing the preexisting business from continuing to operate upon the termination or expiration of the franchise agreement (of course, however, the franchisor could and should cover the add-on business within the restriction).

C. Management Agreement

As discussed above, management agreements are necessary in certain states to address restrictions on the CPOM.[131] In particular, certain states prohibit those without a medical license from owning or having any ownership interest in a medical practice and/or employing medical practitioners. In order to work around these prohibitions, a franchisee without a medical license may establish a relationship with a duly licensed PC and enter into a management services agreement or comparable agreement with the PC, under which generally (a) the PC owns and operates the medical practice, (b) the PC employs the medical staff who provide medical services at the medical practice, (c) the franchisee provides the PC with certain non-medical management and administrative services and support in exchange for which the PC compensates the franchisee for the services it provides.

According to the terms of most franchise agreements, it is ultimately the franchisee's responsibility to determine the laws and regulations that govern the operation of its franchised business and to develop a legally compliant framework for operations. However, most health care franchisors nevertheless provide franchisees with a form management agreement to use. In some cases, franchisors provide a sample form for the franchisee as an exhibit to the FDD or in the operations manual. In other cases, the franchisor actually mandates the form of management agreement that must be utilized (subject to any requested changes proposed by the franchisee's counsel, as may be necessary to comply with applicable law, and subject to the franchisor's approval). Whether a mandatory form or simply an optional base template, providing the management agreement helps to ensure that the franchisee understands the basic regulatory framework and economic model of the business. In addition, given the complexity of operating in a heavily regulated industry, the legal costs associated with navigating such an industry can be significant. Thus, without limitation to the franchisee's responsibility for ensuring the agreement is reviewed by its own legal counsel, providing the sample form will typically reduce the legal start-up costs incurred by the franchisee.

The management agreement should clearly outline each party's roles and responsibilities. The agreement should make clear that the franchisee is not responsible for and is in fact prohibited from (a) providing any actual medical services; (b) supervising, directing, controlling, or suggesting to the PC or its physicians or other medical employees the manner in which the PC

[131] *See* Sections III.A, and IV.A, B, and E *infra*.

provides or may provide medical or urgent care services to its patients; and (c) engaging in any practices that are, or may appear to be, the practice of medicine. The management agreement should also provide that the PC is solely responsible for (a) providing all medical services, and (b) employing and controlling the PC's medical employees (i.e., physicians, nurses, X-ray technicians, medical receptionists, and other employees who will provide patient services). In short, the agreement should outline the basic tenants of the CPOM.

Similarly, the management agreement should outline the precise management services that will be provided by the franchisee. These services often include the design, construction, buildout, and maintenance of the facility; the negotiation of vendor agreements; the procurement, installation, and management of technology systems; payroll and human resource services; billing and collection services; patient scheduling services; bookkeeping, accounting, and tax services; and advertising and marketing. The management agreement should also require that the PC and all of the physicians the PC employs comply with applicable laws, rules, and regulations; maintain their medical licenses; and provide high standards of medical care.

Where the franchisee is responsible for any furniture, fixtures and equipment ("FF&E") in the facility, the agreement should also clarify exactly what FF&E is being provided and under what terms it is being provided. For example, whether the FF&E is being leased to the PC in exchange for separate renumeration, or whether the PC is granted a license to use the FF&E during the term free of any cost or expense. To guard against any CPOM or other related concerns, the agreement should also include self-serving language that the FF&E should be used if and as the PC determines is in the best interest of its patients.

The management agreement should also address potential liabilities through comprehensive indemnification and insurance provisions, which are also discussed in Section VI.B.2 above. Each party should agree to indemnify the other for any claims relating to its respective responsibilities. The PC, therefore, should indemnify the franchisee for any claims arising from the negligence or professional acts or omissions of the PC or any of its employees (e.g., medical malpractice claims), whereas the franchisee should indemnify the PC for any claims arising from any willful or grossly negligent act or omission by the franchisee in its performance of the agreement (e.g., a slip and fall resulting from the franchisee's failure to maintain the facility premises). An indemnification provision must be supplemented by appropriate insurance. The agreement should also detail the particular types of insurance, policy limits and other insurance-related requirements for both the PC and the franchisee.

Finally, the management agreement should address each party's termination rights and corresponding post-termination obligations. In addition to each party's right to terminate upon an uncured breach, the management agreement should enumerate the franchisee's additional termination rights. Because the arrangement is predicated on the PC's medical license, the franchisee must maintain the right to terminate the agreement immediately if, for example, the sole shareholder of the PC dies or becomes disabled or incompetent, the sole shareholder of the PC loses the shareholder's medical license, or if termination is necessary to protect public health or safety. Finally, the agreement should provide that upon termination or expiration, in addition to standard post termination obligations, such as the requirement to return any confidential information and comply with any non-competition covenant (if permissible by applicable law), importantly, the PC must cooperate with the franchisee to assure the appropriate transfer of patient cases and patient records.

D. Business Associate Agreement

As discussed in Section III.F above, HIPAA requirements apply to three kinds of "covered entities," which are (1) health care providers, (2) health care clearinghouses, and (3) health plans. Depending upon the circumstances of each system, the franchisor and/or the franchisee may meet the definition of a "covered entity" and be subject to HIPAA. If a party is a "covered entity" then it must have a written agreement with each of its business associates to address specific issues and aspects of HIPAA requirements.[132] This section focuses primarily on common business associate agreement terms in the franchise context.

A central question is what or who is a "business associate?" The U.S. Department of Health and Human Services provides a useful overview of the business associate issues, as well as other aspects of HIPAA on its website.[133] According to HHS:

> "A 'business associate' is a person or entity that performs certain functions or activities that involve the use or disclosure of protected health information on behalf of, or provides services to, a covered entity. A member of the covered entity's workforce is not a business associate. A covered health care provider, health plan, or health care clearinghouse can be a business associate of another covered entity. The Privacy Rule lists some of the functions or activities, as well as the particular services, that make a person or entity a business associate, if the activity or service involves the use or disclosure of protected health information. The types of functions or activities that may make a person or entity a business associate include payment or health care operations activities, as well as other functions or activities regulated by the Administrative Simplification Rules.
>
> Business associate functions and activities include: claims processing or administration; data analysis, processing or administration; utilization review; quality assurance; billing; benefit management; practice management; and repricing. Business associate services are: legal; actuarial; accounting; consulting; data aggregation; management; administrative; accreditation; and financial. See the definition of "business associate" at 45 CFR 160.103."[134]

With this explanation, it is evident how both franchisors and franchisee in the health care industry, including any systems using the practice management model, can fall into the definition of either a "covered entity" or a "business associate" under HIPAA. As a result, the franchisor may be required to sign a business associate agreement with the franchisee, and franchisees may also be required to enter into such an agreement with the PC for which it provides support services.

Business associate agreements are typically mandated by the franchise agreement and may be included either as an exhibit or in the operations manuals. Business associate agreements must, among other things, (a) describe the permitted and required uses of protected health information by the business associate, (b) restrict the business associate from using or further disclosing the protected health information other than as permitted or required by the

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[132] 45 C.F.R. § 164.502(e) (2024).

[133] U.S. Dept. of Health and Human Svcs., *Business Associate Contracts*, (Jan. 25, 2013), https://www.hhs.gov/hipaa/for-professionals/covered-entities/sample-business-associate/index.html.

[134] Id.

contract or as required by law, and (c) require the business associate to use appropriate safeguards to prevent a use or disclosure of the PHI other than as allowed under the contract.[135]

Additionally, if a covered entity knows of a material breach or violation of the contract by the business associate, the covered entity is required to take reasonable steps to cure the breach or end the violation, and if such steps are unsuccessful, to terminate the contract or arrangement. In some circumstances, the covered entity may be required to report the problem to the applicable authority.[136] It is critical that franchisors evaluate their system and obtain qualified guidance on HIPAA application and relevant requirements. The authors refer the reader to the HHS website for additional information and guidance and sample business associate agreement provisions.[137]

E. Addendum for Add-On Medical Services

As discussed in Section IV.E above, certain businesses are more appropriately equipped to offer a medical service as an optional add-on feature, rather than a mandatory element of the core brand. Significant modifications to franchisor's form franchise agreement are not essential for this purpose, because franchisees of an otherwise traditional service franchise may not wish to offer medical services, or because they fail to meet the franchisor's qualifications to do so. Thus, when a franchisor allows the offering of an optional medical service, an addendum to the franchise agreement devoted to the optional offering may be signed. The advantage of an addendum is straightforward: all terms related to the health care service are provided in a separate document. Should the franchisee and franchisor determine that compliance with local health care laws is impractical, or agree to discontinue the add-on, the main franchise agreement need not be terminated.

The addendum for the add-on service should (a) obligate the franchisee to enter into a management agreement with a licensed medical professional who has the right to supervise licensed medical staff who will administer the service; (b) identify the types of services that the franchisee will provide to the medical professional (e.g., facilities management, patient collections, financial services, patient inquiries and complaints, contract review, and negotiations); and, importantly (c) provide that the revenue the franchisee derives from providing such services to the medical professional is commensurate with the value of the services. The addendum should also provide for the following terms:

- Medical professional shall, at all times, be solely responsible for all aspects of the professional services the professional and the professional's medical staff provide.

- Medical professional is solely responsible for training, professional direction, and supervision of all licensed medical staff; except that the franchisee practice manager shall be solely responsible for employment or engagement of medical professional's staff as the parties agree.

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[135] *Id.*, 45 CFR 164.504(e).

[136] Id. .

[137] *Business Associate Contracts*, *supra* note 133.

- Franchisor may suspend or terminate the addendum immediately upon notice if the medical professional is unable to perform the professional's obligations under the management agreement.

- Medical professional and all licensed medical staff associated with the franchised business shall have and maintain an unrestricted license to practice their profession in their particular field of expertise in the state in which the business is located.

- Medical professional and all licensed medical staff shall have a level of competence, experience, and skill comparable to that prevailing in the community where the medical professional and licensed medical staff provide professional services.

- Franchisor is in no way be responsible for any decisions, acts or omissions related to the optional medical services provided by the medical professionals or licensed medical staff.

- Franchisee shall inform all customers of the business that neither franchisor nor franchisee has any control over or responsibility for any medical director's or medical director's licensed medical professionals' practice of medicine.

- The medical professional is solely responsible for determining which medical services are appropriate to be administered, and that licensed medical staff shall at all times be free, in their sole discretion, to exercise their professional judgment in delivering or performing the optional services.

- Neither franchisor or franchisee are permitted to affect or influence the professional judgment of any medical professional or licensed medical persons.

- Any provision that may be construed or deemed to constitute the practice of medicine or the ownership or control of a medical practice shall be void and waived by franchisor.

VII. REGISTRATION CONSIDERATIONS

A. Franchise Examiner Perspectives

As franchise practitioners who regularly handle state registrations of FDDs are aware, inconsistencies sometime arise between states as examiners interpret the FTC Franchise Rule and Guidelines. This is true for franchises in the professional fields. In California, for example, the DFPI will refer applicants to the California Medical Board for information and guidance to assist franchise practitioners in structuring a management agreement that aligns with California's CPOM doctrine.[138] In the authors' experience, examiners often refer to guidance of state medical authority when reviewing health care franchise applications. Even if the proposed FDD meets state franchise requirements, it does not necessarily mean that the franchise agreement and management agreement will withstand scrutiny from the California Medical Board, even if these agreements appear compliant with state law.

[138] *See* Cal. Med. Bd., *Physicians and Surgeons,* https://www.mbc.ca.gov/Licensing/Physicians-and-Surgeons/Practice-Information/, (last visited Jul. 20, 2024).

B. Required Disclosures

States may also require certain additional disclosures of health care franchisors. It has been the experience of the authors, for example, that the DFPI permits only two types of health care franchises: (1) the franchisor is a professional medical corporation and its franchisees are also licensed physicians; or (2) the franchise concept is purely administrative and does not control any aspect of the physician's practice. Currently, if the DFPI determines that the business model fails to meet either of these standards, as part of the application review and comment process, California may require the following risk factor be included in the California addendum:

> In registering this franchise, the California Department of Financial Protection and Innovation has not reviewed, makes no statements concerning, the franchisor's compliance with state and federal licensing and regulatory requirements relating to the practice of medicine. You should consult with your attorney concerning these laws, regulations and ordinances that may affect the operation of your business. If the California Medical Board, or any other agency overseeing the practice of medicine in this state, determines that the operation of the franchise fails to comply with state law, the franchisor may be required to cease operations of the franchised business in California. This may result in the termination of your franchise and loss of your investment.

More broadly, state franchise administrators may require other disclosures that are more specific to a brand's unique characteristics, and through the review and comment process, ask for supplements to the standard FDD disclosures. For example, if the franchise focuses heavily on specific procedures or reimbursements by Medicare (or other government health programs), a state may require additional risk factors or other disclosures, potentially in Item 19 if there is a financial performance representation, regarding these attributes and the impact of potential changes by the third-party payors.

C. Exemptions Commonly Utilized

The potential to qualify for exemptions and exclusions under the franchise laws are often of considerable interest to franchisors (and potential franchisors) as a means to reduce their regulatory burdens and streamline their sales and operations processes. In specialized fields and heavily regulated industries, the appeal of exemptions may be heightened, both to franchisors and to potential franchisees. The underlying reasons for their interest in exemptions differ but may include the desire to avoid any stigma or bias against being labeled a "franchise" or part of a corporate culture, reducing regulatory time for review by franchise authorities, and reducing the time and resources for franchisee internal legal review of an FDD (such as when a hospital or other large organization elects to add on a licensed program).

The authors focus on select exemptions that most often apply to specialized industries and, more particularly, franchises for health care related services. Namely, (1) "fractional" franchise exemptions (or exclusions from the franchise definition) that may apply when the prospect is an existing operator looking to incorporate a new service or product line; and (2) large and/or experienced franchisee exemptions based on the size, experience and/or resources of the likely franchisee.

D. Exemption Analysis Process

Any exemption analysis will be a two-step process (unless the franchisor's focus is solely on exemptions from state registration requirements). First, does an exemption from the FTC

Franchise Rule apply and eliminate the franchisor's obligation to provide disclosure thereunder? Second, if the franchisor intends to offer and sell franchises in states with state franchise laws, is there an exemption in the applicable states that would eliminate the need to register and/or provide disclosure under state requirements?[139] Because the standards for exemptions are not the same under the FTC Franchise Rule and the state laws, each transaction must be reviewed individually to see whether an exemption applies. The specific criteria of these state exemptions vary significantly, as does the scope of the state exemptions. Some state exemptions require the franchisor to make an annual exemption filing in order to claim the exemption, and others require an exemption be filed for each transaction. Moreover, some exemptions (and exclusions) will relieve the franchisor of registration and disclosure obligations, whereas other exemptions will not eliminate the need to prepare and provide an FDD.

1. Fractional Franchisee Exemptions

The fractional franchise exemption may have the broadest application in the health care and wellness services industries. Under the FTC Franchise Rule, this exemption applies if: (a) the licensee, or if any one of the licensee's current directors or officers or the current directors or officers of the licensee's parent or affiliate has more than two years of experience in the same type of business, and (b) the parties to the transaction had a reasonable basis to anticipate that the sales arising from the franchise relationship will not exceed 20% of the franchisee's total dollar volume in sales during the first year of operation.[140] At the state level, a number of state franchise laws have similar exemptions for fractional franchises or exclude "fractional" businesses from the definition of a "franchise," which may significantly reduce the state regulatory load.[141]

In specialized industries, it is easy to see how this exemption may be relevant, particularly in connection with the wellness and personal care services, which may apply equally to medical providers seeking to add on services and products that are complementary to their main practice (such as a primary care or cardiologist adding rehabilitation services relevant to their patients' health needs), and to non-medical providers seeking to add complementary services that incorporate regulated services (such as a salon and spa adding laser services). This is not, however, limited to add-on services. As franchising in health services continues to expand and feature specialized medical services and equipment, traditional health care providers may find it attractive to add those "fractional" operations to their operations.

2. Large and Experienced Franchisee Exemptions

The FTC Franchise Rule and several states have exemptions that are based on the size and experience of the prospective franchisee. The FTC Franchise Rule's large franchisee exemption applies when the franchise is sold to a business entity with: (a) five or more years of

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[139] For purposes of this discussion, we focus (1) on state franchise laws, without discussion of state business opportunity laws; and (2) with respect to state franchise laws, the state(s) in which the prospective franchisee and the intended franchised business will be located, rather than examining all potential triggers for a state franchise law.

[140] 16 C.F.R. § 436.8(a)(2).

[141] For state fractional franchise exemptions and exclusions, *see, e.g.*, CAL. CORP. CODE § 31108 (2014); 815 ILL. COMP. STAT. 705/3(1)(ii); IND. CODE § 23-2-2.5-1(a) (2015); MICH. COMP. LAWS § 445.1506(h); MINN. STAT. §§ 80C.03(f), 80C.01(Subd. 18) (2014); N.Y. COMP. CODES R. & REGS. tit. 13 § 200.10(2) (2013); R.I. ADMIN. CODE 11-7-2.5; S.D. CODIFIED LAWS § 37-5B-12(3); VA. CODE § 13.1-559; and WIS. STAT. § 553.22(1) (1978); and EXEMPTIONS AND EXCLUSIONS UNDER FEDERAL AND STATE FRANCHISE REGISTRATION AND DISCLOSURE LAWS (Leslie Dawn Curran and Beata Katarina Krakus eds., 2017).

experience, which may be in any line of business; and (2) a net worth exceeding $7,348,000.[142] The experience and net worth of a franchisee entity's parents and/or affiliates (separately or in total) can be used to meet these qualifications.[143] Several states also permit exemptions based on the experience, size, and financial resources (which may include net worth or annual income depending on the state) of the prospective franchisee.[144]

It may be more common to find franchisees that meet these size and experience exemption criteria within the specialized industries discussed in this paper, rather than in traditional franchise systems. For example, as new health care services are developed and franchisors devise efficient support systems, experienced providers such as physician groups, hospitals, clinics, and pharmacies, may wish to expand their offerings to include services and products offered by a franchise system or to be part of the franchise network to obtain enhancements that a franchisor can offer (such as vendor arrangements, technology support, negotiated purchasing contracts, etc.).

VIII. OPERATIONAL CONSIDERATIONS

A. Licensure, Certifications, Accreditation, and Other Forms of Authorization

Within heavily regulated industries, health care providers, insurance brokers and agents, tax preparers, and other service providers in the professions must comply with various requirements relating to licenses, certifications, and credentials before they may provide services to their respective clientele. As a general matter, these requirements derive from state laws and may vary considerably among states. The term "credentialing" is often used to refer to the collective and systematic process of collecting and verifying a health care provider's professional qualifications, licenses, and professional history. Below we provide an overview of what is covered by licensure, certification, and accreditation requirements, with the recognition that these terms may be used differently in various jurisdictions and in informal use.

In general terms, "licensure" refers to a grant of legal authority by a state to practice a profession within a designated scope of practice. The state defines, through its state regulatory authority, the tasks and functions of a profession and requires that these tasks may be legally performed only by those who are licensed by the state. Examples of state requirements to obtain a license include specific educational and training requirements, passing examinations, demonstrating competence to practice safely and effectively, fulfilling continuing education opportunities, and adhering to a code of ethics.

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[142] 16 C.F.R. § 436.8(a)(5)(ii) (2024). Under the FTC Franchise Rule, the FTC is to adjust the thresholds for inflation every four years based on the Consumer Price Index, and the most recent adjustment was effective as of July 12, 2024. 16 C.F.R. § 436.8(b) (2024); 89 Fed. Reg. 57077, 57078 (July 12, 2024). Additionally, the FTC Franchise Rule refers to the licensee as an entity, but FTC guidance indicates that an individual may satisfy this exemption. *See* Statement of Basis and Purpose *in* Disclosure Requirements and Prohibitions Concerning Franchising, 72 Fed. Reg. 15445 (March 30, 2007) ("2007 SBP"), n.845.

[143] *See* 2007 SBP, n.845.

[144] For state large/experienced franchisee exemptions, *see e.g.*, EXEMPTIONS AND EXCLUSIONS UNDER FEDERAL AND STATE FRANCHISE REGISTRATION AND DISCLOSURE LAWS (Leslie Dawn Curran and Beata Katarina Krakus eds., 2017); *see also,* CAL. CORP. CODE § 31106 (2014) (for the large franchisee exemption); CAL. CORP. CODE § 31109 (2024) (for the large franchisee exemption); 815 ILL.COMP. STAT. 705/8(a)(2); R.I. GEN. LAWS § 19-28.1-6(4) (2013); S.D. CODIFIED LAWS § 37-5B-13(2); WASH. REV. CODE § 19.100.240; and WIS. STAT. § 553.235(1) (1978).

In the health care field, states impose licensure requirements on individual physicians and on other types of health care providers and facilities. Additionally, some states require state licenses and approvals for an organization to establish certain types of health care facilities or offer certain types of services, such as providing home health care services. For example, in Virginia, the Virginia Department of Health – Office of Licensure and Certification administers state licensing programs for hospitals, outpatient surgical hospitals, nursing facilities, home care organizations, and hospice programs.[145] The scope of state licensure requirements and the time periods necessary to complete the process and obtain the approvals can vary substantially.

In general terms, "certification" refers to the process by which a non-governmental organization recognizes an individual for meeting the specific qualifications. In the health care field, professional organizations administer or set up independent certifying bodies, which grant a certification or credential recognizing that individuals have demonstrated knowledge of or competency in a particular specialty. The requirements for certification may exceed the competency requirements for state licensing, which are designed to ensure a minimum level of competence. The certification process is usually voluntary, but some states mandate certification as part of the licensure process for specific disciplines.[146]

The term "accreditation" refers to a quality assurance process in which a non-governmental organization evaluates a health care organization to determine whether it meets the accrediting organization's standards. For the most part, accreditation is voluntary, but in some circumstances, accreditation from select accreditation organizations may facilitate participation in certain programs. There are multiple accreditation organizations covering various types of health care providers. One such example with a large reach is the Joint Commission on Accreditation of Health Care Organizations, which purports to be the United States' largest standard setting and accrediting body in health care.[147]

B. Training

Both initial and ongoing training are crucial to the success of a professional franchise. In health care franchises subject to CPOM rules, there will need to be clear delineations of training responsibilities so that non-professionals avoid training the professionals. For instance, a health care franchisor that employs the practice management model may have training that concerns HIPAA, government regulations, administration, retail or back-office functions, and other areas that likewise pertain to medical management services. In view of the significant regulation in health care professions discussed in Section III above, training should address the significance of health care fraud and abuse laws, the resulting limitations on franchisee marketing, and the need to assure accuracy of claims for payment.

Where the training is focused on the management aspects of the franchised business rather than the practice of medicine, one of the training components will invariably be locating and engaging a quality medical professional if one has not already been selected and approved. Franchisee selection is critical for any professional franchise, particularly in the health care industry where the medical service must be delivered effectively. Correspondingly, if the

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[145] Virginia Dep't of Health, *Licensure and Certification – Epidemiology,* https://www.vdh.virginia.gov/epidemiology/licensure-and-certification/ (last visited Aug. 26, 2024).

[146] Inst. of Med., Comm. on the Health Pros. Educ. Summit; Health Professions Education: A Bridge to Quality (Greiner AC, Knebel E, eds. 2003).

[147] THE JOINT COMMISSION, https://www.jointcommission.org/.

franchisor's ownership group includes a medical director, the medical director should be the one administering training to other physicians on medical procedures or particular medical techniques associated with the brand. That said, a non-medical franchisor entity would not be able to mandate use of such technique in a CPOM state.

The two types of training may take place simultaneously at a franchise convention, summit or similar systemwide training event, but in separate places so that physicians are not receiving training from non-physicians. Provided the training sessions are properly segmented and "matched" to the appropriate trainers, both the practice manager and the physician may attend the same convention. The key is respecting the line between health services and operations of the franchised business.

Another concern is "over-training" to the degree of enhancing risk of joint employer or vicarious liability actions. To further manage this risk, third-party organizations or boards can train in HIPAA compliance, to help assure franchisee compliance with technical aspects of HIPAA, as well as government or industry certification. Further separation of the franchisor from instruction in essentially technical aspects of HIPAA requirements can only serve to obey CPOM prohibitions.

C. Marketing

Brand recognition and the ability to harness collective marketing dollars is one of the fundamental drivers of franchising, drawing individuals to join a system rather than striking out on their own. Franchisors in specialized and regulated industries can certainly leverage the brand and assist with marketing. However, they must contend with added regulatory and ethical issues that do not apply to most businesses and be ready to adapt their marketing approaches in a number of ways. As discussed throughout this paper, the laws and guidance governing the health care industry varies significantly by state, practice areas, the type of service or product, the position of the licensed professional, and whether the services are paid for through government funded programs, to name a few. While a full review of the various health care laws that may affect a franchisor's ability to market and advertise is beyond this paper, we focus below on a few issues that may apply broadly based on the types of brand advertising that many systems conduct.

Restrictions on patient referrals and kickbacks can inhibit some marketing activities. As discussed in Section III.B above, the federal AKS provides penalties for anyone who knowingly and willfully offers, pays, solicits, or receives remuneration to induce or reward referrals of business that may be reimbursed under the Medicare or Medicaid programs. Additionally, states have passed similar laws. Considering the growth of online directories and marketing companies focused on health care services, home care services and the like, it is not surprising that over the years, numerous legal actions and cases have alleged improper referral arrangements with medical marketing suppliers.[148] When these laws apply to the services featured in the franchise system, careful examination should be made as to whether any of the marketing expenditures and marketing support services may be characterized as payments to a referral source for each

[148] *See e.g.,* United States ex rel. Lutz v. Mallory, 988 F.3d 730 (4th Cir. 2021) (fines and penalties over $100 million for AKS and FCA violations involving payments by a laboratory company to consulting company that marketed and sold blood tests); Press Release, U.S. Dep't of Just., Home Health Providers to Pay $4.5M to Resolve Alleged False Claims Act Liability for Providing Kickbacks to Assisted Living Facilities and Doctors (July 1, 2024), https://www.justice.gov/opa/pr/home-health-providers-pay-45m-resolve-alleged-false-claims-act-liability-providing-kickbacks; Press release, U.S. Dep't of Just., Marketers and Physicians in Five States Agree to Pay Over $1.5 Million to Settle Laboratory Kickback Allegations (April 1, 2024), https://www.justice.gov/opa/pr/marketers-and-physicians-five-states-agree-pay-over-15-million-settle-laboratory-kickback.

patient referred to the provider by the referral source (such as by lead generation conducted online or by other means).

Additionally, as with other management and practice support services, in some states and circumstances, a provider may not be permitted to pay for marketing services as a percentage of the provider's fees, or in manner directly correlated to revenues from medical services.[149] Whereas other states allow percentage-based marketing fees, if the fees are fair market value for those services and are not for referrals to a specific medical provider[150]. But surely, this is limited to payments to marketing suppliers and does not affect the marketing to the end users? Not so. The referral and kickback laws can also apply to offering gifts, rewards, discounts, and free services to patients. As such, the franchisor may need to adapt its marketing strategy or fee structures.

An aspect that may be less often discussed but also relevant are testimonials and reviews. In the age of digital marketing, leveraging customer reviews is a powerful marketing tool with the ability to drive customers to new businesses. Franchisors around the world use these to their advantage and those in specialized industries, including the health care field, are no different – except that they have additional considerations. As with other industries, health care franchises should be cognizant of the FTC's guidelines for the use of testimonials but should also consider additional guidelines that may apply to the health care providers under professional ethics codes and guidelines.[151] For example, the American Medical Association's ethics guidelines provide, among other things, that testimonials by patients regarding a "physician's skills or the quality of the physician's professional services tend to be deceptive when they do not reflect the results that patients with conditions comparable to the testimoniant's condition generally receive" and "generalized statements of satisfaction with a physician's services may be made if they are representative of the experiences of that of physician's patients."[152] If the marketing personnel charged with developing system-wide marketing materials are not aware of these constraints, it is easy to see how broad use of testimonials for a system could unwittingly create exposure. In addition, all use of testimonials and reviews will need to comply with HIPAA and other privacy laws.

D. HIPAA Compliance

As discussed above, HIPAA imposes requirements intended to protect the privacy and security of patient health information (such as demographic data, information on past, present, or future physical or mental health conditions, health care services provided, and information on past, present, or future payments for the provision of health care), and affords certain rights to patients with respect to their health information.[153]

HIPAA compliance is a challenge in a franchise setting, where franchisors are accustomed to reserving and exercising broad rights over their franchisees. For example, although franchisors often claim ownership over the franchisee's customer data, franchisors in the health care setting

[149] *See* Markenson et al., *supra* notes 27 and 30**Error! Bookmark not defined.**.

[150] 42 CFR § 1001.952.

[151] For the FTC's guidelines on the use of testimonials, *see* 16 CFR part 255.

[152] AMA CEJA Ethics E-5.02.

[153] *See* Sections III.F and VI.D *infra*.

may not want to undertake the responsibility that accompanies this ownership. Further, even where a franchisor does not claim ownership over the franchise's customer data, they must be mindful of the inadvertent ways in which they may come in contact with this information. For example, if the franchisor has access to the franchisee's computer and point-of-sale system, or requires or permits the franchisee to provide a detailed breakdown of services provided to each customer in the franchisee's ongoing reporting requirements, the franchisor may come in contact with the franchisee's customers' PHI, triggering HIPAA obligations. This contact may come even more inadvertently, such as where a franchisor conducts a financial audit of a delinquent franchisee's books and records, or an operational on-site audit or inspection of poor performing franchises. In each case, the franchisor is likely to come into contact with customer PHI.

In order not to run afoul of HIPAA, franchisors who may obtain PHI from their franchisees should enter into a business associate agreement detailing the limitations on the franchisor's use and further disclosure of protected health information, the franchisor's and franchisee's obligations with respect to PHI, how breaches of security related to the protected health information will be handled, and other general contract terms. The terms of a typical business associate agreement are more fully addressed in Section VI.D above.

E. Enforcing System Standards

Franchisors often must impose operational and brand standard controls in order to maintain the uniformity of customer experience that is the bedrock of franchising. However, health care franchisors will be much more limited in their ability to exercise such controls. Given the patchwork of state and federal laws regulating the health care industry, and the different franchise models that may be used concurrently by different franchisees within the same franchise system, drafting and enforcing system standards can be a quagmire for franchisors.

Some CPOM laws are more stringent than others. Where a health care franchisor uses generic, non-state tailored agreements, it must be mindful before actually exercising its contractual enforcement rights that it conducts the necessary diligence not to cross any red lines.

Health care franchisors can generally impose controls related to their trademarks and brand standards, such as approval over site selection, mandated signage used throughout the facility, the use of branded uniforms worn by the staff, etc. However, as discussed throughout the paper, CPOM laws and regulations restrict the franchisor from controlling any medical staff or any element of their delivery of medical services. These restrictions may include dictating the facility's hours of operation, layout, the number of patients seen per day, the medical equipment used in the facility, etc., all of which should remain squarely within the judgment of the PC. These concepts may be addressed in the initial drafting of the documents; however, enforcement may come down to a fact-specific analysis. Imagine a situation where a franchisor conducts an on-site inspection, only to find a facility that is messy and cluttered and poorly portraying the brand. Is this simply a facilities maintenance default, typically within the purview of the franchisee? Or is what the franchisor views as clutter really the PC's preferred layout and organization of medical equipment? In some circumstances, it may be difficult for the franchisor to ascertain the cause of the default and whether it was driven by the PC's judgement or the franchisee's negligence.

Ultimately, while enforcing system standards may be more complex for health care franchisors than for franchisors of more traditional franchise concepts, it is still possible and should not prevent a health care concept from expanding through a franchise model.

IX. CONCLUSION

One commonality to franchising in specialized fields is that each franchisor must be prepared and willing to work through significant regulations and understand the nuances that will affect the operations and economics of its franchises. In the health care field, we are witnessing, in real time, various states trying to harmonize two competing philosophies that are often at odds with one another when it comes to managing the rising costs and accessibility of health care: the societal benefits that come from maximizing profitability and efficiency so that quality health care is available and affordable for the greatest number of people, while simultaneously preserving the independent judgements of the professionals directly responsible for the providing that care.

Given that modern medicine is becoming more commercialized and expensive each year, it is neither shocking nor surprising that some states are becoming more flexible, allowing new structures and easing ownership restrictions (to varying degrees) in ways that may be conducive to franchising and licensing. Many of the objectives and principles that underpin health care laws are germane to other professions and businesses offering specialized services, particularly the legal and accounting fields.

The longevity and success of franchising in specialized and heavily regulated industries may depend to no small degree on how adept franchisors are in developing their systems within the confines of regulations and minimizing backlash to perceived dangers of franchising the specialized services. As private equity investment in these industries increases, and the pressures to allow for franchised systems within them only grow, it will be interesting to observe how the regulatory boards and agencies react and state laws evolve in the coming years.

BIOGRAPHIES

Regina Amolsch is a partner at Plave Koch PLC, a franchise boutique in Northern Virginia, concentrates on franchising and licensing and has over 25 years of experience with a variety of franchise, corporate and business development matters across a diverse range of industries. Regina's experience includes advising on transactional, regulatory and intellectual property issues important in developing and growing franchise programs; drafting and negotiating franchise, development, master franchise agreements and related licenses for domestic and international franchise systems; counseling franchisors with regard regulatory (FDD) compliance and on franchisee relationship issues; and advising on franchise merger and acquisition transactions, private equity investments in franchise systems, and franchise issues in business securitization transactions. Regina has received industry recognitions, including being named to Who's Who Legal - Franchise and The Best Lawyers in America© and has co-authored articles appearing in various franchise-related publications and seminar presentations. Regina is member of the ABA Forum on Franchising and the International Franchise Association.

Dale A. Cohen is a partner at Akerman LLP in New York, New York. Dale focuses her practice on domestic and international franchising, distribution, and licensing law, and advises new emerging brands as well as widely recognized mature brands with respect to structuring and implementing their franchise, distribution, and licensing programs. Dale also has a wealth of experience in franchise-related mergers and acquisitions (including assisting private equity firms with the purchase and sale of franchise systems), sophisticated franchise-related financing transactions (including the securitization of a franchisor's royalty stream), and general corporate law. Dale has been consistently ranked for franchise law in *The Best Lawyers in America*, *Super Lawyers* Magazine, *Franchise Times* and *Who's Who Legal*.

Matthew Soroky is a shareholder at Lewitt Hackman in Encino, California. Matt primarily represents franchisors in start-up and emerging franchise brands and operates as their outside general counsel in regulatory compliance, franchise relationship and transactional matters. Matt has also litigated an array of franchise, business, and intellectual property disputes on behalf of franchisors and franchisees, including franchise disclosure violations, inadvertent/accidental franchise claims, trademark and copyright infringement, and disputes involving distributor, dealer and commercial supply contracts. Matt is recognized as a Certified Specialist in Franchise and Distribution Law by the State Bar of California's Board of Legal Specialization. Matt currently serves as Staff Editor for *The Franchise Law Journal*, and his publications include articles for *The Franchise Law Journal*, *The Franchise Lawyer*, *Los Angeles and San Francisco Daily Journal* and *Valley Lawyer*. He has been nominated as a *Southern California Rising Star* in Franchise and Distribution Law by Super Lawyers each year since 2018.