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Checklist

How To Launch a Femtech/Telehealth Start Up

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Even before Covid-19, Forbes was estimating that Femtech will be a $50 billion industry by 2025, with fertility products being a primary driver. Femtech is a term that applies to a category of software, diagnostics, and other products and services that use technology to focus on women's health. The rise in Femtech can be attributed, in part, to the fact that women drive the vast majority of healthcare decisions in the U.S., and to the fact that they are increasingly demanding products that give them agency over their own biological functions. However, the growth in Femtech, not surprisingly, also corresponds with growth in at-home testing, investment in digital health products, an enormous demand for telehealth solutions, and increasing pressure on private and government insurers to pay for it. Interest in this area is only likely to increase as the tech and healthcare communities continue to innovate in response to Covid-19, and as the pandemic itself drives demand for alternatives to traditional healthcare.

Two questions are top of mind for companies marketing Femtech products—how quickly can we launch, and what should we budget? The answers to those questions will be driven by legal issues in four key areas: FDA issues, intellectual property issues, data privacy and security issues, and state laws governing the delivery of healthcare services. The following is a checklist of legal issues to help Femtech and telehealth companies plan, prior to launch.

FDA Issues

FDA has jurisdiction over medical "devices"—instruments that are intended to diagnose, prevent or treat disease, or otherwise affect the structure/function of the body. The term "device" includes diagnostic test kits, as well as some, but not all, software functions (i.e., apps). The number and extent of legal hurdles presented by FDA's legal framework (i.e., pre-market review and manufacturing controls) are dictated by the level of risk presented to patients by each device function. With that in mind, when developing a health-related app or other digital health product, there are three threshold questions:

- **What types of functions does my product perform?** Many health-related apps and digital health products perform multiple functions. Therefore, the first step is to identify what those functions are. Does the product acquire physiological data (e.g., heart rate, weight, images of a structure within the body)? Does it transfer, display, or store that data? Does it send a patient or a healthcare provider recommendations about a condition or a disease? Does it direct the HCP or patient to take immediate action? Can the HCP or patient review the basis for the recommendation provided by the product? Does the information provided just provide general wellness information (e.g., weight or sleep management)?

- **Does my product have any functions that meet FDA's definition of "device" in the first place?** In an effort to optimize, and not stymie, innovation in the healthcare and tech sectors, Congress recently carved certain types of software functions out of FDA's definition of "device." For example, a software function that is intended only to transfer, store, or display medical device data is not a "device" function regulated by FDA at all. In addition, certain software functions that provide HCPs with clinical decision support are not "devices" if they do not acquire a signal from the body, are merely intended to display, analyze, or print medical data, and if the recommendations they provide to HCP can be independently reviewed by the HCP.

- **If the product does have "device" functions, is FDA actively regulating them?** FDA, like Congress, is also working to ensure that innovation is this space is not stymied by over-regulation. Therefore, FDA is only actively regulating device functions that present higher risk. The following guidance documents explain which types of device functions FDA is actively regulating: FDA's Guidance for Clinical Decision Support Software, FDA's Mobile Medical App Guidance, FDA's Guidance on General Wellness Products, and FDA's Guidance on Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices.

When navigating the questions above, keep in mind that the more a software function is developed beyond merely displaying, transferring, or storing patient data, providing patient education about a disease or condition, or providing general wellness information, the more likely it is to be actively regulated by the FDA. A function designed to acquire physiological signals or direct medical action is prime for FDA regulation.

If a health-related app or other digital health product has a function that is actively regulated by FDA, then certain regulatory requirements will kick in, such as pre-market review by FDA, and it will be important to plan ahead. The costs and time associated with pre-market review will depend on (1) the type of pre-market application required, and (2) whether data is required to support the application.

The type of application and amount of data required will be dictated by the level of risk presented by the device and its degree of novelty. Lower risk products that are similar to other products on the market, may be able to submit a 510(k) application, which typically requires less data and has a faster review clock at FDA (i.e., approximately 116 days); lower risk products that are completely novel often require de novo applications, which typically require some data and have a slightly longer review clock (i.e., approximately 150 days); and the higher risk products will require premarket approval applications (PMAs), which typically require more data and have the longest review clocks (i.e., approximately 310 days).

IP Issues

Although compliance with FDA's regulatory process ensures that a company has permission to market a device, a cultivated intellectual property portfolio provides protection for the device once it is on the market. An internal audit of all of the IP related to a product before launch can help identify any holes in your portfolio before they become a problem. When auditing for potential holes, it is important to ask the following questions.

- **Could there be an infringement problem when the product launches?** To neutralize some potential patent-related problems before launch, a company can perform a Freedom to Operate (FTO) analysis. This process involves searching issued and pending patents to obtain a legal opinion as to whether a product, process or service might be considered to infringe any patents owned by others. If the FTO analysis reveals that another party's patents may limit the launch of the product, there are a number of options to address the situation, including purchasing or licensing the patents, cross-licensing, or creating a design-around in order to avoid infringement. A trademark analysis of similarly named products can also help avoid naming issues once the product has launched.

- Is my product protected from competition? Many companies innovating in Femtech and telehealth already have policies in place to document the invention process and to file for patent protection during the development of a new product. However, the product may change over time as it goes through testing and trials, and the final product may differ from the scope of the claims in the originally filed patents. It is important to review all patents and pending applications related to the product to ensure that what is claimed appropriately covers the product in its final form. To the extent there is a discrepancy between the final product and what has been claimed, filing amendments or continuing applications can close the gap and make sure there is adequate protection.

- Who owns the rights to my software? When using a third-party developer to help design a health-related app or digital health product it is important to understand the ownership of the intellectual property of the finished product. For example, the third-party developer may use code that it created or already used for other customers and may be hesitant to give up ownership rights. It is also important to understand how the use of open-source code may affect your ability to protect it. To the extent a third-party developer creates unique code for the product, they may be more willing to assign ownership rights for the project. Obviously, if a product is developed entirely in-house, this eliminates the risk of third party claims to the ownership rights of the software.

- Are internal trade secret protections in place? If there are any trade secrets associated with the product, access must be restricted from day one in order for trade secret protections to apply. It is important to set up a secure location to store the information and limit access to that location by taking specific precautions, such as: ensuring that anyone who is given access to the trade secret information has signed an agreement to keep the information confidential, keeping a complete list of everyone who has access

to the information, performing periodic checks on who has access to the secure location and determining whether each person still requires access, and removing access to the secure location if an individual no longer needs access to the trade secret information.

Performing an internal audit of these and other IP issues related to the protection of a new product prior to launch will help avert IP disputes once the product hits the market.

Data Privacy and Security Issues

There are a patchwork of federal and state requirements governing health-related apps and digital health products, in the privacy and security space. Here, there is one threshold question that companies should ask to sort out which set of laws apply.

- **Is the product being marketed direct-to-consumer or to the health care sector (e.g., HCPs)?** When a health-related app, digital health product, or telehealth platform is targeted at the direct-to-consumer space, it may be submedical—meaning that it may not require the involvement of HCPs or implicate the practice of medicine. When the market is purely consumer, the product will be primarily subject to state and federal consumer protection laws. Consumer protection laws are designed protect the consumer from unfair or deceptive trade practices. From a privacy and security perspective, companies selling products that do not involve HCPs must provide explicit privacy policies that describe how any data collected is used and disclosed. Further, the company must maintain reasonable security measures to protect any such data. Any breach of personally identifiable information requires notification to the individual affected. In recent years, there has been a push from certain states, led by California, to pass more stringent consumer protection laws. The goal of these laws is to provide the consumer with more rights to control how their sensitive data is used, disclosed, or sold; but those laws, of course, also place more responsibilities on companies.

In contrast, when a health-related app, digital health product, and/or telehealth platform is targeted at the traditional health care space, the federal Health Insurance Portability and Accountability Act and associated state medical privacy and security laws will generally govern. In many cases companies marketing a health-related app, digital health product, or telehealth platform will be considered a "business associate" and may only use or disclose data as permitted under their agreements with the payers and providers.

From a compliance perspective, these companies will have to draft HIPAA compliant privacy and security policies, designate individuals within the company to oversee the privacy and security program, and train employees on compliance with the policies and procedures. In addition, it is not uncommon for covered entities to push more robust security obligations, such as HITRUST certifications, on these types of companies.

State Law Issues

Various state laws will come into play if a company's device requires a prescription or the company wants to offer health care services through an app, internet platform, or other vehicle. Determining what laws will apply and how they will affect the enterprise should begin with identifying what services the company will offer. The company should also select 3–5 states where they may operate and determine whether state licensure requirements apply to persons delivering the services in those states. Understanding applicable licensure requirements in the state where customers are located may lead to business plan changes—often enhancing profitability. In turn, identifying whether licensed or unlicensed persons will provide the services may affect how the company must structure its business, whether Medicaid or commercial health insurance must cover a device and company services, and other important matters. A lot of time, money, and frustration can be saved if a company methodologically asks and resolves a series of questions like those below while developing its business plan.

- **Do the states where my potential customers reside permit delivery of the service my company wants to deliver?** Each state decides whether a health care-related service may be provided to state residents. For example, over 40 states permit "dry needling," some states are silent, and the remainder, including California and New York, prohibit it.

- **Do state licensing laws dictate who can provide the service?** To determine whether licensing is required it is helpful to ask whether the service involves one or more of the following, which all states agree require a license: diagnosing, treating, or prescribing. If the company engages in one of these through lay persons or artificial intelligence, it may be charged with a felony—practicing medicine without a license.

- **Diagnosing.** As mentioned above, if the company's device is "intended to diagnose" under the FDA analysis discussed above, then the company may decide to forego direct-to-consumer business and deal only with licensed HCPs, advise prospective customers to see their personal physician for interpretation of diagnostic test results, or affiliate with physicians or other licensed HCPs who are permitted to diagnose under state law. If the device is not intended to diagnose but provides fitness or "general wellness" information the involvement of a licensed professional probably is not required.

- **Treating**. Whether a device or service provides "treatment" under state law usually depends on whether the conduct falls within the scope of a licensed profession, but it may depend on how regulatory agencies and medical boards define the term. "Treatment" may mean addressing a disease, affecting bodily functions, or something more like enhancing general wellbeing. While FDA focuses on devices designed to prevent disease, many states regulate more broadly to include services designed to promote or maintain "wellness." These states may require licensing for weight-loss coaching whether provided to a person suffering from obesity or another disease or to a healthy person trying to lose their "Quarantine Fifteen." Whether a service is within the scope of a licensed profession is usually more straightforward. By way of example, in some states, only chiropractors can perform dry needling and in other states a physical therapy license is required. As another example, anyone at the company could provide sleep coaching in any state without a license or certification. Understanding each state's definitions is important to ensure that unlicensed individuals are not crossing a line, for example when an unlicensed "health coach" gives nutritional advice that only licensed dieticians may provide.

- **Prescribing**. If the company's product or device requires a prescription, the need to associate with certain licensed HCPs will be clear: Licensed physicians or nurse practitioners can prescribe in any of the fifty states where they are licensed, but registered nurses and others cannot. Some states, but not all, allow licensed Physician Assistants to prescribe, and others add advanced registered NPs to the list. Each state law must be examined.

- **How can I develop relationships with qualified HCPs who are appropriately licensed in each state where my customers reside?** Twenty-nine states, together with Washington, D.C., Guam and more to be added soon, participate in the Interstate Medical Licensure Compact. Such compacts allow physicians to become licensed in multiple states if they are in good standing in one. The Nurse Licensure Compact allows registered nurses to practice in 34 states if they are licensed in one, although NPs do not have a similar compact yet. Many healthcare professionals take advantage of compacts like these so that they can be licensed to practice in multiple states. Practicing across state lines is predicted to rapidly become easier and more seamless over the next three years.

- **What telehealth laws should I understand?** Except during the current public health emergency, all telehealth lawsprohibit the delivery of health care services for which a license is required to persons within a state where the HCP is not licensed. Otherwise, state telehealth laws address primarily whether certain conduct is prohibited or "unprofessional," which may subject a licensed HCP to discipline; and whether the HCP is entitled to payment from Medicaid and commercial health plans. Relevant to the first category, for example, a physician in Louisiana may lose their license for providing health care services by phone alone. In most states, however, providing services by phone without video just means the provider may not get paid by a health plan. All states require Medicaid plans to cover telehealth services and the majority of states require coverage by commercial plans. This creates opportunities for telehealth companies. But these laws need not drive the company's operations; if a state requires coverage only for synchronous (real time) video encounters, that does not mean that asynchronous (store-and-forward) or telephone encounters are prohibited or that they cannot be billed to consumers. Other important telehealth laws include those addressing the extent to which a physician-patient relationship may be

formed via telehealth; patients must be located in rural or specified qualifying sites; patients must provide consent, whether it may be written or oral, and the required content; and other constraints may affect company plans, such as the requirement in many states that physical therapists may only provide services based on referrals.

- **What other laws do I need to understand before entering into arrangements with physicians and other clinicians?** Understanding whether the states selected enforce the Corporate Practice of Medicine Doctrine is critical to structuring the company's relationship with HCPs. In general, this doctrine prohibits lay entities from employing and otherwise controlling HCPs' medical decisions and seeks to ensure that HCPs are not influenced by financial considerations. Contract relationships in which lay entities are providing support services to the HCPs in exchange for payment at the fair market value of those services usually avoid CPM concerns. Typically, HCPs create professional corporations in which lay entity start-ups have no equity, and the start-ups provide websites, apps, access to devices, and other services to the PC, including advertising, accounting, and collections. These kinds of arrangements can solve other problems that tech companies must address such as anti-kickback and fee-splitting concerns. Where the doctrine applies, it applies to physicians, and in some states to psychologists, physical therapists, and other HCPs.

In sum, once the services to be offered are known, state law should be mined to determine who may provide those services, and if licensure is required, the permitted scope of practice. Some healthcare-related services may only be provided by licensed physicians, while others can be provided by licensed NPs, psychologists, social workers, physical therapists, other HCPs who may be less expensively employed without violating any CPM laws, or unlicensed coaches. A start-up can benefit by tailoring its services to state law; it may choose to employ social workers in one state and contract with psychologists in another to deliver essentially the same services.