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Delivering Health Care Services to Consumers through eHealth Devices: The Role of State Professional Practice Laws

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Smart medical devices that can deliver health care services are increasingly consumer friendly. Using the latest technologies and sophisticated algorithms, some devices are capable of collecting data directly from consumers then providing them with diagnoses and prescriptions for treatment, equipment and products. Companies producing these devices are eager to market and deliver their products and services directly to defined demographic consumer groups for certain low-risk health conditions. The marketing campaigns and business models they use for national expansion, including how licensed practitioners are involved, depend upon the application of state professional practice laws.

Professional practice laws govern who can collect patient data, administer tests, make diagnoses, determine treatment plans and issue prescriptions, among other things. These laws vary by state and are based on product-by-product and professional license-by-license categories. The laws may dictate the relationship between the device and licensed practitioners and ultimately determine a company's organizational structure. Further, professional practice laws may define the content of advertising for the medical devices and the health conditions they address. Typically, violations of these professional practice laws are classified as misdemeanors.

Many of these laws were enacted decades ago when legislators never contemplated telehealth and the advanced technology of today's medical devices. Often, state professional licensing boards will apply the laws to these innovative devices – even if the laws may not specifically address them; for example, they may allege that the device company is illegally engaged in the practice of medicine. Where a board determines that the device services can be delivered only by licensed practitioners or takes actions that effectively exclude the device company from the market, the board's motivations need to be scrutinized. Although a professional licensing board (comprised of the practitioners the board regulates) can protect the public's health and safety, a board cannot engage in anticompetitive conduct aimed at protecting their own financial interests as licensed practitioners. *See North Carolina Board of Dental Examiners v. Federal Trade Commission*, 135 S. Ct. 1101 (2015).

Where these state laws do apply, their lack of uniformity forces companies to develop national regulatory strategies that include flexible business models and advertising disclaimers tailored to differing state requirements. Companies may opt to use two or more business models in order to maximize their profits through direct to consumer sales to the extent it is legally possible. Alternatively, companies may choose to design only one business structure in a manner that complies with the most restrictive state laws, despite the arrangement being the non-preferred option.

These business models frequently include employing or contracting with licensed professionals or telehealth networks, who can provide the professional services associated with the device. Other business arrangements involve direct relationships with licensed practitioners for their use of the devices in their own practices. The models used will vary based upon whether a state has corporate practice of medicine laws that prohibit lay corporations from employing or controlling licensed professionals. *See, e.g.*, California Bus. & Prof. Code, § 2400, New York CLS Bus Corp § 1507.

New medical devices in the ophthalmic industry illustrate the interplay between state professional practice laws and advanced technological devices. Consumers can now take on-line refractive examinations using computers and smartphones (*Opternative*). They can also use handheld devices and a computer and collect and transmit their refractive exam data from their homes, with the help of a technician (*Blink*). Although the devices may be capable of issuing prescriptions based on the consumers' data, the companies enlist licensed vision care practitioners to write the prescriptions that are electronically transmitted to consumers, in order to comply with professional practice laws. In New York, that practice has proven to be insufficient in warding off allegations of professional practice law violations. The New York Optometric Association has requested state regulators to investigate whether Blink's use of unlicensed technicians to help consumers use the handheld devices violates New York's laws.

As an increasing number of devices change the dynamics between consumers, device companies and practitioners' traditional areas of practice, state laws will need to respond to consumer demand for direct device delivery of certain health care services. Until such time as the laws address these new technologies, companies are advised to develop national business and marketing strategies that address professional practice law restrictions and incorporate licensed health professionals into their business models.

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