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State Law Obstacles to the National Distribution of eHealth Medical Devices Directly to Consumers

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The latest and greatest eHealth medical devices directed to consumers are technologically advanced and consumer-friendly. They have the capacity to diagnose certain health conditions and generate treatment plans and prescriptions—without licensed health care practitioners. State professional practice laws often require that licensed practitioners be involved with the consumer's use of these sophisticated devices. These laws vary by state and product category, making it difficult for companies to use one national business model. Prior to entering the market, companies with these device types are advised to develop strategic regulatory plans, business models and government relations strategies, based on their assessment of state professional practice and telehealth laws.

eHealth Medical Devices

Using eHealth medical devices, consumers can receive care at their convenience and in their location of choice, by using devices and Internet software that collects and transmits data to the device company or its designee. For instance, Opternative, Inc. offers an online refractive eye exam (as compared to a comprehensive, ocular health exam) in 27 states. A consumer between the ages of 18 and 40 who meets specified health conditions and has a computer and a smart phone can purchase the refractive exam and receive a digital eyeglass prescription for $40 and a contact lens prescription for $20 more. Licensed practitioners review the collected data and approve the prescriptions before electronically transmitting them to patients as state laws require. The company's website states that its clinical study shows that the online refractive exam was statistically equivalent to a refractive exam in a licensed practitioner's office. Licensed practitioners are not convinced, however. In Michigan, they convinced legislators to ban the use of automated eye exams.

The nature and extent of a licensed practitioner's involvement with an eHealth medical device will depend on the device's capabilities and each state's professional practice and telehealth laws.

State Professional Practice Laws

Violations of state professional practice laws may be classified as misdemeanors. These laws require that persons who perform or offer to perform certain medical tests, make diagnoses and provide treatment, including prescriptions for ancillary products, have appropriate state professional licenses. Device companies that advertise and sell consumers devices that perform any one of those acts and that are not used by or under the supervision of licensed practitioners, may be illegally engaged in the professional practice related to the device. Likewise, unlicensed persons affiliated with the device company who help consumers perform tests using the device may violate the professional laws or aid and abet others who do so.

Corporate practice of medicine laws may restrict how companies structure their business relationships with licensed practitioners. Where these laws exist, they govern whether the company can employ or contract with licensed practitioners.

EHealth device companies need to determine the applicability of each state's professional practice laws to their devices prior to developing their business models and marketing plans. Depending on the device, there are various models that companies can consider, including telehealth, brick and mortar clinics with management services arrangements and franchise approaches.

Telehealth Laws

Medical device companies can use telehealth approaches to involve licensed practitioners in the delivery of care with their devices. Using the device-generated data, licensed practitioners located remotely may be able to make patient diagnoses and sign prescriptions, in compliance with state law.

State telehealth laws vary with regard to licensure, informed consent, commercial reimbursement parity, the establishment of a physician-patient relationship and location restrictions, among other things. Licensure laws that require remote practitioners to be licensed in the state where the patient is located, create barriers to efficient national telehealth models.

Two bills pending in Congress seek to eliminate licensing restrictions with regard to Medicare and Department of Veteran's Affairs health professionals. The TELE-MED Act (H.R. 3018 and S. 1778) and the Veterans E-Health & Telemedicine Support Act or VETS Act call for providers delivering those services to be licensed in only one-state. If these laws pass, they may encourage states to enact laws that provide for reciprocity in licensure for other services that are not reimbursed by a government program.

Compliance with Marketing and Advertising Laws

Companies marketing eHealth devices that could infringe upon a practitioner's scope of practice should proceed cautiously when entering new markets. Professional competitive dynamics can easily lead to legal and political challenges to consumers' use of the devices without the involvement of licensed professionals. Device companies should be diligent in ensuring that all marketing and advertising claims are accurate and properly substantiated; any device limitations, e.g., user restrictions, should be adequately and conspicuously disclosed. Strict compliance in these areas may help to alleviate health and safety challenges from practitioners and regulatory boards to the business model used.

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