**Digital Health Law Update**—An Overview of Notable Happenings Affecting Digital Health, Mobile Health, and Telemedicine
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## Industry Insights

Jones Day partners Todd Kelly and Elizabeth Myers and associate Eric Jackson recently coauthored an article titled "While Rules Evolve Telemedicine is Alive and Well in Texas," published in *Texas Lawyer*. The article explores various telemedicine models that are being used in America's second most populous state, despite the uncertainty and litigation disputes regarding recent amendments to the Texas Medical Board's rules on telemedicine and prescribing that threaten some direct-to-consumer delivery models. The article concludes that "little has changed consultations among licensed providers or referrals by physicians who have already evaluated the patient."



## Federal Features

**ONC**—The Office of National Coordinator for Health Information Technology ("ONC") recently released a white paper, titled *Designing the Consumer-Centered Telehealth & eVisit Experience: Considerations for the Future of Consumer Healthcare*, which ONC had commissioned as a summary of its April 2015 design workshop on the topic.

According to the paper, the workshop identified the following nine guidelines for consumer-centered telehealth.

- There cannot be friction for the user.

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UPCOMING EVENTS

**October 21, 2015**: Maureen Bennett will give a presentation on *International Clinical Research Issues* to the Boston Bar Association's Health Law Education Committee.

**October 26–27, 2015**: Alexis Gilroy will speak about *Lessons on Telemedicine—Opportunities and Unique Diligence and Payment Considerations* at the AHLA Health Plan Counsel Institute in Chicago, IL.

**November 19–20, 2015**: Cathy Livingston will present on *Compensation Issues and*

- Team-based care must include smart triggers.
- Real world and online world must converge.
- We must be sensitive to data overload.
- Consumers are the hubs of their own health care data.
- Converge data for interactions to be safe and meaningful.
- Expand role for care team based on new data triggers.
- Integrate technology and human interaction in the physical world.
- Increase focus on patient data security.

Although the paper explains that it should not be interpreted as a policy statement of ONC, it does provide an overview of the state regulatory landscape, other challenges faced by telehealth providers, and general principles for what it describes as four levels of the integration-to-fracturing of care:

(i) integrated care (primary care provider ("PCP"), patient, and family members); (ii) telehealth-enabled care (use of telehealth by same PCP); (iii) extended integration (telehealth-enabled encounter with networked providers); and (iv) outside care (telehealth-enabled encounters with "one-off" clinicians, i.e., no preexisting relationship). The white paper indicates that ONC expects to continue discussing these issues and has a stated goal of expanding the adoption and use of telehealth and mobile health.

**FTC**—On September 17, 2015, the Consumer Protection Bureau of the Federal Trade Commission ("FTC") released details of a recent enforcement action against the marketers of a mobile application that provides visual exercises focused on reading and other activities. Under the terms of a proposed settlement, the company has agreed to disgorge $150,000 and to stop making certain claims about the app. The FTC had alleged that the company did not have scientific evidence to support its claims that the app could improve users' vision. This action serves as a reminder of the importance for careful consumer disclosures and registration terms, especially for mHealth apps.

**Telehealth Legislation**—Members of Congress and outside organizations continue to discuss the Telemedicine for Medicare (TELE-MED) Act of 2015, which has been introduced in both the House of Representatives and Senate. The bill would enable physicians licensed in one state to provide care remotely to Medicare patients located in other states without obtaining a license in the patient's state. Although limited to Medicare services, the bill has a similar purpose as other initiatives aimed at streamlining professional medical standards, such as the Interstate Medical Licensure Compact, which has been adopted by 11 states.

## State Summaries

**Alabama**—On August 19, 2015, the Alabama Board of Medical Examiners announced it had repealed and immediately suspended enforcement of its telehealth rules, explaining the decision was based on its concerns regarding potential antitrust issues following the recent U.S. Supreme Court decision in *North Carolina State Board of Dental Examiners v. FTC*. The repealed rules included an "appropriate physical examination" requirement that limited the use of certain telehealth delivery models in the state. The Board is not expected to issue replacement rules until the state legislature approves new telehealth legislation, possibly as early as spring 2016.

*Joint Ventures, Subsidiaries, and Contractual Issues* at the Western Conference on Tax Exempt Organizations in Los Angeles, CA.

### DIGITAL HEALTH LAW UPDATE ARCHIVES

Digital Health Law Update, Vol. I, Issue 4

Digital Health Law Update, Vol. I, Issue 3

Digital Health Law Update, Vol. I, Issue 2

Digital Health Law Update, Vol. I, Issue 1

### RELATED PRACTICE

Digital Health & HIT

**Colorado**—On August 20, 2015, the Colorado Medical Board issued new guidelines on the appropriate use of telehealth in the context of "direct to consumer" business models. The guidelines closely track the Model Policy of the Federation of State Medical Boards by providing that a provider–patient relationship can be established via telehealth and that the same standard of care applies to both telehealth and in-person delivery models. Other notable features include: (i) the definition of "telehealth" covers both synchronous interactions and store-and-forward transfers; (ii) the use of telehealth requires informed consent with appropriate disclosures on the modality; (iii) a formal written protocol must be developed for handling emergency services; and (iv) recommendations of medical marijuana may not be made via telehealth technologies.

**Idaho**—The Idaho Board of Medicine recently adopted "Guidelines for Appropriate Regulation of Telemedicine." The guidelines mark a significant reform for a state that has been the source of relatively high-profile enforcement actions against telehealth providers. Specifically, the new policy recognizes that a physician–patient relationship may be established remotely but advises physicians not to render medical advice or care using telemedicine without verifying the location of the patient, disclosing the provider's identity and credentials, and obtaining any special informed consents regarding the use of telemedicine technologies, among other requirements. The Board is in the process of codifying these policies into regulations and held a public hearing on the matter on September 15, 2015.

**North Carolina**—Pursuant to a new rule effective August 1, 2015, North Carolina pharmacists are permitted to use professional judgment in refusing to fill a prescription in cases where the prescription order's accuracy, validity, or authenticity or the patient's safety is at issue. Additionally, the rule provides that a prescription order is valid "only if it is a lawful order for a drug, device, or medical equipment issued by a health care provider for a legitimate medical purpose, in the context of a patient–prescriber relationship, and in the course of legitimate professional practice." Previously, state law had imposed an obligation on pharmacists to decline prescriptions when it was believed the prescriber had not conducted "a physical [in-person] exam" of the patient. This change helps bring the pharmacy regulations in line with current policies of the state Medical Board as it relates to telemedicine.

**South Carolina**—At its August 3, 2015 meeting, the S.C. Board of Medical Examiners approved a telemedicine provider guidance document and updated its advice on establishing a physician–patient relationship as a prerequisite to prescribing drugs. The guidance document clarifies that telemedicine is held to the same standard of care as in-person services. With respect to establishing a physician–patient relationship, while the Board's updated guidance indicates that such a relationship can be established solely through telemedicine, the guidance appears to require the use of patient-site ancillary providers where there is no preexisting physician–patient relationship (with limited exceptions such as writing admission orders for a newly hospitalized patient, prescribing for a patient of another licensee for whom the prescriber is taking call, and others).

**Virginia**—Virginia recently amended its rules regarding telemedicine prescribing. As of July 1, 2015, a prescriber may establish a practitioner–patient relationship through "two-way, real-time" communication or store-and-forward technology if the licensed prescriber has a medical history available for review, makes the diagnosis at the time of prescribing, and conforms to standards of care for in-person treatment, among other requirements.

**Wisconsin**—In a notice dated September 21, 2015, the Wisconsin Medical Examining Board announced it has begun the process for proposing new telemedicine regulations. The current administrative code is silent with regard to telemedicine, but the proposed rule would define the practice of telemedicine, explain how a valid physician–patient relationship can be established in a telemedicine setting, and specify licensure and technology requirements for the use of telemedicine. The notice cites federal bill H.R. 691 (Telehealth Modernization Act of 2015) as a model for the issues that will be addressed by the Wisconsin proposed rule.

## Reimbursement Review

**Delaware**—In September 2015, the Delaware Division of Medicaid and Medical Assistance ("DMMA") adopted an amendment recognizing the Medicaid beneficiary's home as an originating site for reimbursement of interactive, real-time audio-video telemedicine. In response to public comments, the DMMA also revised the final rule to include nonresidential day programs and alternate locations as originating sites.

**Michigan**—On September 16, 2015, Michigan legislators introduced Senate Bill No. 495, which would require coverage for asynchronous store-and-forward and real-time telemedicine provision of care as long as the provider is licensed in the state where the patient is located. Additionally, the legislation would clarify that insurance policies may "not require face-to-face-contact" for telemedicine services to qualify for reimbursement.

**Texas**—Effective September 1, 2015, an amendment to Texas Medicaid Rule § 355.7001 clarifies that physicians will be reimbursed for telemedicine services provided in a school-based setting even if the physician is not the patient's primary care provider. To qualify, the child must be located at school and enrolled in Medicaid. A health professional, such as a school nurse, must be present with the child during treatment, and the parent or guardian must give consent before the telemedicine services are provided.

**Washington**—The Washington Apple Health (Medicaid) program recently held a public hearing regarding a proposed rule that would cover "HIPAA-compliant, interactive, real-time audio and video telecommunications (including web-based applications) or store and forward technology [used] to deliver covered services that are within his or her scope of practice to a client at a site other than the site where the provider is located." Eligible originating sites would include clinics, hospitals, and patients' homes, among other listed locations. As the proposed rule goes though the rulemaking process, the program has temporarily implemented a less expansive rule that covers only real-time audio and video telemedicine.

## Global Happenings

**EU Digital Single Market—**On September 23, 2015, the European Commission launched a public consultation on Standards for the Digital Single Market ("DSM"). Andrus Ansip, Commission Vice President for the Digital Single Market, explained that common standards and interoperability will "make the best of fast-growing sectors such as cloud computing and the Internet of Things." The Commission is gathering views on priorities for standards in key technology areas that are, in the Commission's opinion, critical to achieving the DSM and, once delivered, can constitute a technological foundation upon which other standards can be built. eHealth is one of the key topics on which the Commission is looking for input. Public comments are due December 16, 2015. Please contact Cristiana Spontoni if you are interested in discussing how we can assist you with submitting comments.

**EU–US Data Protection**—Telehealth providers hoping to bridge the North Atlantic face challenging issues for cross-jurisdictional compliance in the area of data protection. As a general principle, EU Directive 95/46/EC and national implementing legislation prohibit the processing of personal data related to health, except in certain conditions, such as obtaining the explicit consent of the data subject or where processing is required for the purposes of preventative medicine or medical care and is performed by health care professionals subject to confidentiality obligations. In the United States, the real issue concerning data protection is often which authorities apply: U.S. Department of Health and Human Services or Federal Trade Commission regulations, state-specific data privacy rules, or all of the above. This topic is explored in an August 2015 article in *eHealth Law &*

*Policy*, coauthored by Jones Day partners Alexis Gilroy, Cristiana Spontoni, and Undine von Diemar and associate Katherine Llewellyn.

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