



DIGITAL HEALTH LAW UPDATE

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Industry Insights

Digital Health Transactions—Are You Doing Your Due Diligence?

With investment in digital health start-ups growing exponentially in recent years, it is important that interested parties proceed with a transactional perspective attuned to the unique regulatory environment of this industry. Investors, strategic partners, and others looking to acquire a stake in the action are typically well versed in the standard business and legal due diligence conducted in connection with financings, M&A, joint ventures, and other transactional matters. However, the unique challenges facing digital health companies can often present unforeseen areas of regulatory and operational risk that may be overlooked in a standard due diligence review.

The legal issues faced by digital health companies can run the gamut but frequently involve complex analyses of state-based laws relating to the practice of a health care profession (e.g., corporate practice and fee-splitting prohibitions, licensure, standard of practice, e-prescribing, and informed consent) as well as federal and state laws relating to the privacy and security of health data, fraud and abuse, FDA oversight, and product liability. Companies operating in multiple states will often be required to comply with varying and, in some cases, vague or conflicting laws and regulations across such states. These laws can not only create significant potential liability for the unwary, they can also affect the financial assessment and value of a target company to the

CONTACTS

[Alexis S. Gilroy](#)

Washington

[Soleil E. Teubner](#)

San Francisco

[Scott A. Edelstein](#)

Washington / Los Angeles

[Kevin D. Lyles](#)

Columbus

[Stephen E. Gillette](#)

Silicon Valley

[Maureen Bennett](#)

Boston / San Francisco

[Indradeep Bhattacharya](#), [Matthew R.](#)

[Bowles](#), and [Jessica Jardine Wilkes](#)

assisted in the preparation of this Digital Health Law Update.

[Detailed Contact Information](#)

UPCOMING EVENTS

Telemedicine Investor & Strategic Summit

May 4, 2015

Los Angeles, CA

[More Information](#)

Other Events

May 1, 2015: [Scott Edelstein](#) will speak on "Legal Considerations in International Cross-Border Telemedicine" at the National Center for Healthcare Leadership's US Cooperative for

extent the company will need to modify its operations or be restructured to comply with such laws.

Given the complex and rapidly evolving regulatory requirements implicated in the digital health arena, it is not uncommon for these emerging companies, despite their best intentions, to nonetheless fail to achieve compliance with many of such requirements or otherwise not be aware of how the requirements may apply.

As a result, it is critical for investors, strategic partners, and others to identify these regulatory considerations during the due diligence process as a means not only to understand the potential liabilities a target company may face, but also to determine whether the target should be required to modify its operations or structure pre- or post-closing of the transaction.

Federal Features

EHR Programs—Last month, the Centers for Medicare & Medicaid Services ("CMS") and the Office of the National Coordinator for Health Information Technology ("ONC") issued their latest updates to federal initiatives promoting greater utilization of electronic health records ("EHRs"). CMS issued a [proposed rule](#) to implement Stage 3 of the Medicare and Medicaid EHR Incentive Programs, which encourages meaningful use of EHRs in clinical settings. Stage 3 will require most participating providers to submit clinical quality measurement data beginning in 2018. ONC's new [certification criteria](#) for EHR technology (2015 Edition) focuses on [interoperability](#) and promoting enhanced data portability, transitions of care, and application programming interface, or API, capabilities.

Telehealth Legislation—On April 21, 2015, the technology subcommittee of the Senate Committee on Commerce, Science & Transportation held a hearing on "[Advancing Telehealth Through Connectivity](#)," which focused on efforts by private sector and government entities to advance digital health, particularly in rural areas. Subcommittee member Roger Wicker (R-MS) indicated his plans to reintroduce the Telehealth Enhancement Act, a bill that would expand Medicare coverage for hospital telehealth services and allow accountable care organizations to seek Medicare Advantage reimbursement for telehealth and remote patient-monitoring services. The bill was not passed during the previous Congress.

21st Century Cures Act—Proposed legislation, titled the 21st Century Cures Act, aims to accelerate the discovery, development, and delivery of innovative medical therapies. According to an original [discussion document](#) by the House Energy & Commerce Committee, the bill would allow the Secretary of Health and Human Services to waive certain restrictions on Medicare coverage of telehealth services, including the originating site requirements, geographic limitations, and type-of-provider restrictions. However, recent reports from industry sources indicate lawmakers are planning to remove these telehealth provisions from the bill. Although an updated discussion document has not yet been released, the House Subcommittee on Health is scheduled to hold a [legislative hearing](#) on the bill on April 30, 2015.

VA Telehealth—The Department of Veterans Affairs ("VA") recently submitted its fiscal year 2016 budget, proposing to earmark \$1.2 billion specifically for telehealth efforts, a nearly 10 percent increase from the prior year. The VA plans to expand telehealth operations to include audiology, intensive care, mental health, pathology, and radiology.

International Patient Programs event in Denver, CO.

May 3–5, 2015: [Scott Edelstein](#) and [Alexis Gilroy](#) will speak at the [American Telemedicine Association's Annual Meeting](#) in a program titled *Telehealth Partnering in US & Abroad—A Look at Viable Strategies & Legal Considerations*. [Doug Pearson](#), [Bruce Olcott](#), and [Chris Mikson](#) will speak at a pre-conference session titled *Digital Health in Transition: Regulatory Insights for Product Developers*.

RELATED PRACTICE

[Digital Health & HIT](#)

State Summaries

Interstate Medical Licensure Compact—The [Interstate Medical License Compact](#) (the "Compact") has now been adopted by six states, including [Utah](#), [Idaho](#), [West Virginia](#), and [Montana](#), which have passed enabling legislation since our last *Update*. By its own terms, the Compact must be enacted in at least seven states to become effective. Eleven other states have introduced enabling legislation. Follow the status of these bills and learn about the Compact at www.licenseportability.org.

Arkansas—On April 1, 2015, Arkansas enacted the [Telemedicine Act](#), which requires providers using telemedicine to (i) be licensed in Arkansas (except for episodic consultation services) and (ii) have an existing professional relationship with the patient based on a prior in-person examination (except for certain provider consultations and cross-coverage arrangements with the patient's regular treating professional). Effective January 1, 2016, the Act also requires certain health benefit plans to cover services provided using telemedicine on parity with coverage for in-person services.

Idaho—Last month, Idaho's governor signed the [Idaho Telehealth Access Act](#) into law. The Act, effective July 1, 2015, allows a provider to establish a provider-patient relationship using two-way audio and visual interaction, as long as the applicable standard of care is satisfied in each instance. A provider with an established provider-patient relationship (including as established through real-time video and audio engagement) may prescribe noncontrolled substances using telehealth services. The law also includes a specific informed consent requirement.

Mississippi—On March 23, 2015, the Mississippi Board of Medical Licensure proposed an [amendment](#) to its regulations, which would define "telemedicine" as "secure videoconferencing or store and forward technology" and sets standards for telehealth providers, including a specific list of components for informed consent. Notably, the proposed rule would require physicians providing telemedicine services in Mississippi to establish a formal agreement with a Mississippi-based health entity that can manage any needs for in-person care arising from the telemedicine examination.

Tennessee—[HB 699](#) awaits the governor's approval. If signed, the legislation would establish an equal standard of care among services provided by both telemedicine and traditional in-person methods, effective July 1, 2015. Notably, the legislation prohibits any health care board or licensing entity from establishing a more restrictive standard of professional practice for services furnished by telehealth.

Texas—This month, the Texas Medical Board adopted [rules](#) amending its Telemedicine Rules (TX Admin. Code, 22, Chapter 174) and its Disciplinary Guidelines (TX Admin. Code, 22, Chapter 190). The amendments (i) expanded the options for providing "telemedicine medical services" for mental health patients to allow for some services at a patient's home regardless of an in-person evaluation and (ii) clarified the Board's requirements on establishing a provider-patient relationship to require either (a) an in-person exam or (b) a face-to-face exam (for which a real-time video and audio modality would be appropriate). Reacting to significant press around the amendments, the Board issued a [press release](#) to provide assistance in interpreting the modified rule. Further, the American Telemedicine Association provided [commentary](#) on the rules and highlighted concerns about the confusing nature of the rules when proposed. The rules take effect June 3, 2015, unless the state legislature overturns them.

Reimbursement Review

State Reimbursement—Three states recently took action to enact reimbursement-related laws:

- Last month, the governor of [Colorado](#) signed a telemedicine parity law restricting health benefit plans from requiring in-person contact between a provider and patient for coverage of telemedicine services. The law takes effect January 1, 2017.

- [Virginia](#) amended its telemedicine parity law to modify the definition of "telemedicine services" to include "electronic technology or media, including interactive audio or video." Private health insurance must now accommodate a broader set of modalities other than video and audio.
- Starting January 1, 2017, the state of [Washington](#) will require public and private health plans to cover services provided by telemedicine (real-time or store-and-forward) in cases where they would cover the same services in-person. Coverage for store-and-forward models requires a related face-to-face follow-up visit, which can be provided by telemedicine.

Global Happenings

India—In March 2015, the Union government announced that 41 government medical institutions will participate in a [task force network](#) aimed at addressing doctor shortages in rural India. The network will facilitate online consultations between medical colleges and peripheral health facilities, offering direct care to patients and educational resources for practitioners. Coinciding with this initiative, the India Medical Association has sponsored a "[Telemedicine Day](#)" to promote widespread adoption of digital solutions to the nation's health care challenges.

South Korea—The Ministry of Health & Welfare is facilitating a pilot program to expand telehealth services directly to patients in remote locations. Previously, South Korea restricted such services to consultations between health care practitioners at clinics. If the program is successful, it could be adopted as permanent law.

United Kingdom—The 2015 UK Budget included plans for significant investments in the "Internet of Things" ("IoT"), such as digital health. UK Chancellor of the Exchequer George Osborne also announced a £20 million funding boost in the budget for four health and social care information projects, including the "Connected Health Cities" initiative, which aims to assemble data, experts, and technology to generate new information that will help shape health and social care in England's northern regions. Some industry analysts predict that net revenue generated from IoT services could range from £800 billion to £1.5 trillion by 2020, and a significant aspect of this would be in health care services. Recent research published in the *British Medical Journal* found that using telehealth devices to monitor patients' health reduced hospital admissions by 18 percent and deaths by 46 percent (compared with usual care). The UK government's announcements are therefore part of a broader policy agenda to institutionalize digital technologies in health care services. In the past year, the National Health Service has been subject to significant cutbacks in funding, and digital technology is widely seen as a means to partly address the funding gap.

Jones Day Digital Health Law Contacts

Alexis S. Gilroy

Washington
+1.202.879.5552
agilroy@jonesday.com

Soleil E. Teubner

San Francisco
+1.415.875.5709
steubner@jonesday.com

Scott A. Edelstein

Washington / Los Angeles
+1.202.879.5572 / +1.213.243.2160
sedelstein@jonesday.com

Kevin D. Lyles

Columbus
+1.614.281.3821
kdlyles@jonesday.com

Stephen E. Gillette

Silicon Valley
+1.650.739.3997
segillette@jonesday.com

Maureen Bennett

Boston / San Francisco
+1.617.449.6884 / +1.415.875.5772
mbennett@jonesday.com

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