

Digital Health Law Update—An Overview of Notable Happenings Affecting Digital Health, Mobile Health, and Telemedicine

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DIGITAL HEALTH LAW UPDATE

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What Does the Interstate Medical Licensure Compact Mean for Telemedicine?

On May 19, 2015, Alabama and Minnesota became the seventh and eighth states, respectively, to enact the Interstate Medical Licensure Compact, joining Idaho, Montana, Utah, South Dakota, Wyoming, and West Virginia. Adoption by the seventh state means the Compact is now effective for the adopting states, and a commission is being formed to enact its terms. Meanwhile, 10 other states have introduced similar legislation.

After a physician has achieved full licensure in at least one Compact-member state, the Compact's streamlined process of expediting licensure in Compact-member states allows a physician desiring to provide services via telemedicine to more quickly open their "virtual doors" to patients. Physician licensure requirements, including for telemedicine, are tied to the location of the patient at the time of the encounter. As such, licensing has long been a hurdle to multistate telemedicine programs as professionals first must be licensed in various locations, which involves administrative processes and timelines that differ by jurisdiction, and often requires duplicative materials and wait-times of anywhere from two months to two years. The Compact would allow eligible physicians to forgo these repetitious processes and avoid significant time delays in Compact-member states. Follow the status of these bills and learn more about the Compact.

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UPCOMING EVENTS

American Health Lawyers Association In-House Counsel Program and Annual Meeting

June 28–July 1, 2015 Washington, D.C.

June 28, 2015: Alexis Gilroy and John Kirsner will be speaking at the In-House Counsel program, Alexis on "Telemedicine—Practical Insights for Considering Regulations and Documentation when Managing Telemedicine Operations and As licensure requirements are linked to the location of the patient, it is important for telemedicine providers to (i) use careful disclaimers on where the provider's services are available, and (ii) confirm the location of the patient prior to each telemedicine encounter. Additionally, as the Compact streamlines medical licensure, keep in mind that CMS and Joint Commission "credentialing by proxy" processes may also streamline provider requirements for privileging of telemedicine providers serving certain health facilities." The "credentialing by proxy" process is a specific structure allowed for telemed by CMS and JC and has been in place since 2011; it often is tied to licensing processes of telemed providers.

Federal Features

21st Century Cures—On May 21, 2015, the House Energy & Commerce Committee voted unanimously to advance H.R. 6, the 21st Century Cures Act, which aims to accelerate the pace of innovative medical therapies through a variety of regulatory reforms. By a 51–0 vote, the Committee approved the bill with a new amendment earmarking billions of dollars in funding for the National Institutes of Health and the Food and Drug Administration.

Transactions," and John on "Bridges and Battlefields: Issues in Unified Medical Staffing Models."

June 29, 2015: Gerry Griffith will be speaking at the Annual Meeting program on "Who's on First—Sorting Out Conflicting Fiduciary Duties in Today's Extended Family Model Health Care Systems."

June 30, 2015: Lisa Han will be speaking at the Annual Meeting program on "New Managed Care Strategies and Concerns over Clinically Integrated Networks and ACOs."

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This version of the legislation features significant changes from prior drafts, such as the addition of interoperability measures for health IT systems and the removal of certain telemedicine reforms. For example, instead of relaxing the originating-site and type-of-provider restrictions on Medicare reimbursement of telehealth services (as originally proposed), the bill now simply calls on the CMS to submit a report to Congress, examining the current use of telehealth and recommending new billing codes for telehealth-delivered procedures that should be covered by Medicare. The bill also explains the "sense of Congress" that health care professionals be licensed where their patients are physically located, although, as drafted, this language would have no binding effect. The House is expected to consider H.R. 6 for a floor vote in June 2015; meanwhile, Senate counterpart legislation remains in committee.

Medicare Coverage Proposal—Members of Congress continue to explore options for expanding Medicare reimbursement of remote health care services. In May 2015, Sen. Mark Kirk (R-IL) introduced S. 1465, which would expand access to stroke telehealth services under the Medicare program.

VA Telehealth—On May 21, 2015, Reps. Charles Rangel (D-NY), Glenn Thompson (R-PA), and 11 other cosponsors introduced H.R. 2516, the Veterans E-Health & Telemedicine Support Act of 2015. Similar bills were introduced in 2012 and 2013 but not enacted by Congress. The current proposal would allow qualified health professionals of the U.S. Department of Veterans Affairs (the "VA") to practice telemedicine across state lines. Under existing law, the VA can waive state licensure requirements for treatment only if the provider and patient are located in a federally owned facility.

State Summaries

Overview—The American Telemedicine Association ("ATA") recently released two updated reports detailing telehealth regulation and practice disparities among the states.

One report uses 13 different indicators to compare coverage and reimbursement practices, and the other report examines state licensure and medical board standards for physician groups. The District of Columbia, Maine, New Hampshire, New Mexico, Tennessee, and Virginia received the highest ratings for policies that encourage telehealth adoption. Connecticut and Rhode Island are the lowest scoring states in that category. Twenty-two states received the highest scores on the standards and licensure report, whereas Alabama and Texas received the lowest scores.

Iowa—The Iowa Board of Medicine has adopted a new rule, effective June 3, 2015, to establish the standards of medical practice via telemedicine. "Telemedicine" is defined to include practicing medicine "using electronic audio-visual communications and information technologies...including interactive audio with asynchronous store-and-forward transmission" between a patient and physician and does not include providing medical services through audio-only phone, email, fax, or mail. Physicians using telemedicine to treat a patient in Iowa must have an active Iowa medical license and will be held to the same standards of care and professional ethics as required of in-person care. A prior inperson examination is not required if telemedicine technology is sufficient to provide an informed diagnosis. Additionally, the Rule provides standards for physicians practicing telemedicine regarding patient consent, follow-up care, coordination of care, emergency services, and patient feedback.

Indiana—The Medical Licensing Board of Indiana adopted a new rule to establish standards for the Board to implement a telehealth pilot program. In part, the rule requires that telehealth consultations include a documented patient evaluation summarizing the visit and the diagnosis. The evaluation may be forwarded to the patient's care providers to encourage continuity of care and must include methods or tools the physician used to assist in the initial history and physical exam.

Louisiana—In late 2014, Louisiana Medical Board adopted regulations specific to telemedicine placing limitations on telemedicine, including restricting the prescribing of controlled substances via telemedicine. In response to those regulations, the Louisiana legislature issued House Concurrent Resolution No. 4 on May 21, 2015, expressing its intent for previously passed telemedicine legislation, HB 1280, that the standard of care for telemedicine services be equal to the standard of care applied generally for medical services and that Medical Board actions should not exceed the scope of the legislative authority.

Tennessee—HB 699 has been signed into law and requires an equal standard of care among services provided by both telemedicine and traditional in-person methods, effective July 1, 2015. The law prohibits any health care board or licensing entity from establishing a more restrictive standard of professional practice for services furnished by telehealth.

Texas—In the wake of new telemedicine rules from the Texas Medical Board amending its Telemedicine Rules (TX Admin. Code, 22, Chapter 174) and its Disciplinary Guidelines (TX Admin. Code, 22, Chapter 190), Dallas-based telemedicine provider Teladoc filed an antitrust lawsuit on April 29, 2015 in the U.S. District Court for the Western District of Texas in Austin. The lawsuit alleges that the Texas regulations illegally limit competition by requiring an in-person visit before a physician may provide telemedicine services and restricting the locations where telemedicine services may be rendered. On May 29, 2015, the District Court granted Teladoc a preliminary injunction enjoining the Texas Medical Board from taking any action to implement, enact, or enforce the modified Rule 190.8 during the pendency of the claims by Teladoc against the Texas Medical Board.

Reimbursement Review

Overview—Recently, the ATA reported that 27 states and the District of Columbia have enacted "parity" laws requiring comparable coverage and reimbursement for telemedicine services as is available for in-person services. Indiana, Minnesota, and Nevada are the latest states to enact such legislation. Additionally, the Oregon House and Senate passed parity law SB 144, and the bill is on its way to the governor. On the federal level, recent

CMS data reveals that Medicare paid \$14M in claims for telehealth services in 2014, out of \$615B total reimbursements.

State Reimbursement—In addition to the four states noted above that adopted parity laws, New Hampshire recently introduced SB 112, which would require Medicaid reimbursement for telehealth services. The bill passed the state Senate but is still in committee in the House. Additionally, California introduced SB 289, which would expand its telemedicine parity law so that insurers must cover patient management services through telephonic or electronic means starting in January 2017. This measure is similar to the CMS chronic care management payment option that began this year.

Private Payors—United Healthcare announced that it will now cover telehealth physician visits via Doctor on Demand, American Well's AmWell, and Optum's NowClinic, available on computers, mobile devices, and smartphones 24 hours a day. This program enables enrollees of United's self-funded employer health plans to choose from in-network virtual care provider groups, speak with a physician, and obtain a diagnosis and/or prescriptions. Coverage will expand to individual plan participants in 2016.

Global Happenings

e-Health Week-In May 2015, during the Latvian Presidency of the Council of the European Union, the Latvian capital of Riga hosted the 2015 e-Health week. The event saw more than 2,000 global decision-makers from public and private health care sectors, clinicians, hospital and IT managers, and other delegates from the EU's 28 Member States come together to discuss emerging trends in digital health. Topics included cooperation between EU Member States, patient involvement, and privacy and data protection. In his keynote speech, Vytenis Andriukaitis, European Commissioner for Health and Food Safety, highlighted digital health's contribution toward prevention, health risk management, and sustainable health care together with the potential for digital health to assist in overcoming today's challenges in the European health care sector, namely: the rise in chronic diseases, increases in health risk factors, and Europe's aging population. Commissioner Andriukaitis also addressed the challenge of finding the right balance between quality, safety, and confidentiality issues while maintaining sufficiently low barriers for innovation. Finally, the Commissioner took the opportunity to discuss the relevance of the recently adopted European Commission Communication, A Digital Single Market Strategy for Europe (discussed below). In particular, the Commissioner made reference to the initiatives to reinforce trust and security in handling personal data, actions related to interoperability and standardization, and supporting an all-inclusive eSociety.

European Union—On May 6, 2015, the European Commission adopted a Communication, *A Digital Single Market Strategy for Europe*, which sets out 16 initiatives to be delivered by the European Commission by the end of 2016. Each of the 16 initiatives falls under one of three pillars upon which the digital single market strategy is built: (i) promoting better consumer and business access to digital goods and services across Europe; (ii) creating the right conditions and a level playing field for digital networks and innovative services to flourish; and (iii) maximizing the growth potential of the digital economy. Of particular interest to digital health is an initiative under the third pillar, "boosting competitiveness though interoperability and standardization." In pursuit of this initiative, the European Commission commits to launch an integrated standardization plan to identify and define key priorities for standardization—with health (telemedicine and mobile health) specifically identified as a focus area.

United Kingdom—The UK government and NHS England have issued a worldwide call for

expressions of interest from innovators who want to test their technology ideas to deliver health care services at scale and in a real clinical setting. The move is part of the government's "combinatorial innovation" project, which aims to identify around five "test beds" that will receive national support for implementing high-potential innovations that respond to clinical needs and increase efficiency in health care services delivery. While the project is looking for innovations in all technology areas, there is a sharp focus on digital technologies and data. The UK Chancellor has indicated that at least one of the test beds identified through the program will focus on enabling Internet of Things technologies. The move is the latest push by the UK to integrate digital health technologies into the NHS. The application process closes on June 12, 2015, and partnerships are to be finalized by the end of the year.

In another matter, Ofcom, the UK's regulator of the communications industry, recently announced a plan to auction off additional mobile spectrum in order to deal with the nation's growing demand for 4G content, including mobile health care. Globally, by 2017, mobile health revenue is expected to reach \$23B across all stakeholders-mobile operators, device vendors, health care providers, and content and application players. The newly available spectrum to be auctioned by Ofcom is currently used by the UK's Ministry of Defense, but it is being made available as part of a wider initiative to free up public sector spectrum for civil uses. However, some have expressed competition policy concerns about the auction, especially at a time of increasing consolidation in the sector.

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