Telehealth In 2017: What Changed And What's Ahead

By Kristi Kung and Matthew Shatzkes December 20, 2017, 10:59 AM EST

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As the U.S. shifts from a fee-for-service (FFS) system to a value-based system, health care information technology will become an increasingly important component in fostering patient engagement, coordinating care, increasing access to services and decreasing overall costs. Telemedicine, in particular, is viewed by many as the solution for achieving access to care and cost-efficiency. Concluding 2017, this article looks back on some of the legal and regulatory changes that occurred with respect to telemedicine as well as areas of interest to watch in 2018.

State-Level Changes

On Dec. 15, 2016, the Federation of State Medical Boards (FSMB) released their "2016 State Medical Board Survey" which was completed by 57 of the 70 state medical licensing boards in the U.S. and its territories, identifying their most pressing issues.[1] The FSMB reported that 75 percent of boards chose telemedicine as one of the most important regulatory topics of 2017, securing the top spot in the survey. This report rang true this year as many licensing boards reconsidered existing telemedicine rules or created new telemedicine licensing frameworks altogether.

In-Person Examination Requirements *(Texas[2], Oklahoma[3], Indiana[4] and Michigan[5])*

Indiana and Michigan each passed laws removing requirements for an in-person examination prior to prescribing via telemedicine. The Michigan law is more expansive and applies to all prescriptions. To prescribe controlled substances via telemedicine in Indiana, however, the patient must have been examined in-person by a licensed Indiana health care provider and the prescriber must have reviewed that provider's treatment plan and issued a prescription pursuant to that plan.

Up until recently, Texas remained the last holdout state requiring an in-person visit before delivering health care services via telemedicine.[6] In May, SB 1107 was signed into law, eliminating the requirement for a "face-to-face" consultation to initiate a

physician-patient relationship. In November, the Texas Medical Board issued new regulations implementing the statutory changes.

Originating Sites

Several states relaxed restrictions on eligible originating sites (Arkansas[7], Hawaii[8], Texas[9], Vermont[10]) for telemedicine, permitting services in locations such as patient homes and schools. Arkansas revised its definition of an “originating site” to “anywhere a patient is located,” while Texas removed its requirement that telemedicine services only be provided at “established medical sites.” Hawaii and Vermont each added patient homes and other nonmedical sites to the definition of “originating sites.” Louisiana removed its requirement that physicians practicing telemedicine maintain an office in the state or contract with in-state providers[11].

Adoption of Telemedicine Practice Acts

Three states (New Jersey[12], Illinois[13], Wisconsin[14]) that previously did not formally address the provision of telemedicine services adopted new frameworks. New Jersey enacted SB 291 explicitly authorizing health care providers to provide telemedicine services so long as a provider-patient relationship has been established. An initial in-person examination is not required; however, the provider must review the patient’s medical history and available medical records prior to the initial telemedicine encounter. Illinois’s Public Act 100-0317 created the Telehealth Act which permits the provision of telemedicine by Illinois-licensed health care professionals. Previously silent with regard to telemedicine practice, new Wisconsin board rules now define telemedicine, explain how a valid physician-patient relationship can be established in a telemedicine setting, and identify technology requirements for physicians who use telemedicine.

Reimbursement Expansion

Many states (Arkansas, Hawaii, Indiana, Minnesota, Montana, Nebraska, Nevada, New Hampshire, New Jersey, North Dakota, Ohio, Pennsylvania, South Dakota, Tennessee, Utah, Vermont, West Virginia, and Wyoming) revised their Medicaid regulations to expand reimbursement for telemedicine services. In addition, several states enacted parity laws with respect to commercial payors or their Medicaid programs, or both, requiring coverage and/or reimbursement of telemedicine services to the same extent as services delivered in-person.

Despite this expansion trend, both North Carolina[15] and South Carolina[16] clarified that their Medicaid programs will not reimburse for store-and-forward and placed further limitations based on the location of services. New Hampshire’s Medicaid reimbursement for telemedicine also has significant limitations, adopting Medicare’s coverage policies with respect to modalities, originating sites, eligible services and distant sites.[17]

Expansion of Telemental Health

There were many state-level advancements in telemental health relating to the provision of services, reimbursement and prescribing. In particular, licensing boards across the country have noted a lack of access to mental health services by certain populations and a desire to reach those individuals through the use of technology. For example, in New York, telehealth regulations were relaxed to enable mental health providers to treat some patients online in certain patient care settings. Under the new Texas telemedicine regulations, restrictions on the provision of mental health services via telemedicine were relaxed and the list of eligible service providers was expanded.

Public Safety

Other states made slight changes to their telemedicine requirements to balance public safety concerns: (1) Alaska implemented regulations requiring businesses to register with the Telemedicine Business Registry prior to providing telemedicine services to patients located in the state[18]; (2) Connecticut passed a law prohibiting prescribing of ocular lenses without an in-person eye examination[19]; and (3) Texas regulations include both a requirement to provide a notice of privacy practices as well as a limitation on the issuance of prescriptions via telemedicine for the treatment of chronic pain[20].

Status of Interstate Medical Licensure Compact

The Interstate Medical Licensure Compact (IMLC) is an agreement between participating states and their licensing boards to qualify physicians to practice medicine across state lines, if they meet the agreed upon eligibility requirements. The licensure application process is expedited by leveraging the physicians' existing information submitted in their state of principal license. Once qualified, the physician may select any number of compact states where they desire to practice. Four states passed laws to join the IMLC in 2017 (Washington, Nebraska, Tennessee[21] and Maine. IMLC's application process officially went live on April 6, 2017, and its first license was issued on April 20, 2017.[22] Compact legislation has also been introduced in Michigan, Rhode Island, Texas, Washington, D.C., and Guam.

Status of Parity Laws[23]

Additional states enacted parity laws in 2017 (Nebraska, New Jersey, North Dakota and Vermont) and others amended their parity laws to remove originating site restrictions (e.g., Arkansas and Washington).

Currently, 34 states and D.C. have some form of parity law for telemedicine and another eight states have proposed parity legislation (Idaho, Kansas, Iowa, Ohio, West Virginia, Pennsylvania, North Carolina, Massachusetts.)

Reimbursement Changes

Medicare

No changes were made to Medicare's statutory coverage of telemedicine or its implementing regulations. However, the annual updates to the Medicare Physician Fee Schedule included the new codes for end stage renal disease (ESRD) services, advanced care planning services, and critical care consultations, that are now eligible for reimbursement if other Medicare coverage criteria are met.

Medicaid

Currently, 48 states and D.C. provide some coverage for telemedicine in their Medicaid FFS.[24] Despite this seemingly widespread coverage, however, the states widely differ in terms of the telemedicine services covered, the provider types covered, location of the patient, form of telemedicine delivery, and overall geography. New Hampshire, for example, only offers telemedicine services to Medicaid beneficiaries within rural areas as defined by Medicare guidelines.

Nevada and Hawaii joined the ranks of state Medicaid programs that reimburse for store-and-forward services and Kentucky and Hawaii now reimburse for remote patient monitoring. As noted above, Arkansas, Hawaii, Indiana, Minnesota, Montana, Nebraska, Nevada, New Hampshire, New Jersey, North Dakota, Ohio, Pennsylvania, South Dakota, Tennessee, Utah, Vermont, West Virginia, and Wyoming amended their Medicaid reimbursement policies for telemedicine to offer expanded coverage.

Employer-Sponsored Health Plans

Commercial plans have expanded their coverage of telemedicine services under employer-sponsored health plans, particularly with respect to behavioral health services. Health care represents an enormous expense to U.S. employers — averaging $12,229 per employee, or 14 percent of total payroll, according to the 2017 Mercer National Survey of Employer-Sponsored Health Plans.[25] The Mercer survey further noted that 71 percent of employers with 500 or more employees offered coverage for telemedicine services, up sharply from 59 percent last year, and this number is expected rise as employers seek to control health care costs.

Federal Expansion of Telemedicine

Federal Bills

Several telemedicine bills were advanced in Congress this year; however, none have been enacted.[26] The Senate unanimously passed the Creating High-Quality Results and Outcomes Necessary to Improve Chronic (CHRONIC) Care Act of 2017 (S.870) in September and it now sits in the House Subcommittee on Health.[27] The CHRONIC Care Act includes four important telemedicine provisions: (1) Medicare Advantage plans may include additional telemedicine services in their bids; (2) certain accountable care organizations (ACOs) have additional flexibility to provide telehealth; (3) beneficiaries receiving dialysis treatments at home may do their monthly check-in visit via

telemedicine; and (4) removes Medicare's originating site coverage restriction for evaluations of an acute stroke. For its part, the House advanced three separate bills this year with provisions similar to those included in the CHRONIC Care Act: expanding telemedicine services under Medicare Advantage (HR 3727), expanding telemedicine for stroke patients (HR 1148), and expanding the use of telemedicine to facilitate the use of home dialysis (HR 3178). Given the bipartisan support for these bills in each chamber, telemedicine advocates are hopeful for legislation in the near future.

FCC: Repeal of Net Neutrality and Increased Funding for Rural Broadband

Net neutrality rules provide that internet service providers cannot speed up, slow down or block any content, applications or websites. On Dec. 14, 2017, the Federal Communications Commission voted to repeal the net neutrality rules resulting in considerable uncertainty about how this change will affect the health care industry, particularly related to telemedicine. FCC Chairman Ajit Pai has argued that the government's light touch approach to high-speed internet will be a net benefit for telemedicine. Industry experts, however, worry that the FCC's reforms will be problematic for health care providers, telemedicine vendors and patients, all of whom require robust connectivity to meet the demands of video consultations that could come at a higher cost. Continued attention should be paid to this heading into 2018.

The FCC has issued a request for public comment to its proposal to increase the $400 million annual cap on the Rural Health Care Program (RHCP).[28] The purpose of the RHCP is to subsidize the difference in rates between rural and urban areas for telecommunication services and as of 2012, to also provide a flat 65 percent discount on certain communications services "to promote the use of broadband services and facilitate the formation of health care provider consortia." The increased funding for broadband expansion to rural areas could dramatically improve telemedicine delivery in areas where access to care is most limited.

FDA: New Digital Health Policies

The U.S. Food and Drug Administration released four new digital health policies aimed at encouraging digital health innovation[29]: (1) The Digital Health Innovation Action Plan[30]; (2) The Clinical and Patient Decision Support Software[31]; (3) The Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act;[32] and (4) The Software as a Medical Device: Clinical Evaluation.[33]

Opioid Epidemic

Individuals suffering from substance abuse often encounter extreme difficulties maintaining sobriety after their discharge from inpatient detoxification facilities. Telemedicine has been successful in engaging this population in continuous monitoring and preventing relapse. When President Donald Trump declared the opioid epidemic a national public health emergency, the declaration provided "for expanded access to telemedicine services, including services involving remote prescribing of medicine

commonly used for substance abuse or mental health treatment." Updates to various state and federal laws, including the Ryan Haight Act[34], will be needed to reflect the president's new opioid order.

Conclusion and Predictions for 2018

The telemedicine landscape experienced significant changes over the past year, primarily at the state level. We expect additional changes in the near future as the health care marketplace incorporates telehealth into population health strategies, making it critical for businesses in this space to stay abreast of evolving regulations.

As we look ahead to 2018, here are a few things that we expect to see evolving on the telehealth front: (1) continued IMLC involvement by states; (2) continued expansion of telemedicine reimbursement in state Medicaid and commercial plans; (3) phasing out of telemedicine pilot programs by health systems and transitioning into comprehensive telemedicine strategies system-wide; (4) increased adoption of remote monitoring services; and (5) integration of health apps into patient care and gamification of health and wellness through mobile apps.

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[1] See "FSMB Survey Identifies Telemedicine as Most Important Regulatory Topic for State Medical Boards in 2016", dated Dec. 15, 2016, available here: https://www.fsmb.org/Media/Default/PDF/Publications/20161215_annual_state_board_survey_sesults.pdf.

[2] See, SB1107 (http://www.legis.state.tx.us/BillLookup/History.aspx?LegSess=85R&Bill=SB1107) (May 2017); see also 22 TAC 174.1 et seq. (November 2017)

[3] See, SB 726 (http://www.oklegislature.gov/BillInfo.aspx?Bill=sb726), effective Nov. 1, 2017.

[4] See, HB 1337 (https://iga.in.gov/legislative/2017/bills/house/1337#digest-heading), effective July 1, 2017.

[5] See, SB 213 (https://www.legislature.mi.gov/documents/2017-2018/publicact/pdf/2017-PA-0022.pdf), effective March 31, 2017.

[6] This year Oklahoma adopted telemedicine practice standards that now explicitly permit the establishment of a physician-patient relationship via telemedicine without an in-person examination. See, SB 726, available at: https://legiscan.com/OK/text/SB726/id/1608914, (May 10, 2017.)

[7] Arkansas passed and signed into law SB 146 on Feb. 20, 2017, amending the state's telemedicine laws to redefine "originating site" to permit services to be provided wherever the patient is located at the time of the consult. See the changes to The Telehealth Act, available here: http://staging.arkleg.state.ar.us/ftproot/bills/2017R/public/SB146.pdf; see also, Act 203 (http://www.arkleg.state.ar.us/assembly/2017/2017R/Acts/ACT203.pdf)

[8] Hawaii passed SB 2395 in 2016, effective as of Jan. 1, 2017, to, among other things, remove originating site restrictions to permit patients to seek telemedicine care in their homes and at other nonmedical sites. See changes to the Telemedicine Act, available here: http://www.capitol.hawaii.gov/session2016/bills/SB2395_CD1_.HTM.

[9] See, SB 1107 (http://www.legis.state.tx.us/tlodocs/85R/billtext/pdf/SB01107F.pdf#navpanes=0)

[10] Vermont added the following new "originating site" definition: "Originating site" means the location of the patient, whether or not accompanied by a health care provider, at the time services are provided by a health care provider through telemedicine, including a health care provider's office, a hospital or a health care facility, or the patient's home or another nonmedical environment such as a school-based health center, a university based health center or the patient's workplace. See new SB 64 language, available here: http://legislature.vermont.gov/assets/Documents/2018/Docs/ACTS/ACT064/ACT064%20As%20Enacted.pdf.

[11] See, LAC 46:XLV.408.

[12] See, SB 291 available at: http://www.njleg.state.nj.us/bills/BillView.asp?BillNumber=S291, effective July 1, 2017.

[13] See, Illinois Public Act 100-0317, available at: http://www.ilga.gov/legislation/publicacts/fulltext.asp?Name=100-0317, effective July 1, 2018.

[14] See, Wisc. Med. Board, Rule 15-087, available at: https://docs.legis.wisconsin.gov/code/register/2017/737B/register/final/cr_15_087_rule_text/cr_15_087_rule_text.

[15] See, NC Div. of Medical Assistance, Medicaid and Health Choice Manual, Clinical Coverage Policy No.: 1H.

[16] See, SC Health and Human Svcs. Dept., Physicians Provider Manual, p. 2-54 (August 2017).

[17] See, NH Stat. 167:4-d, I (Sec. 43:1).

[18] See, SB 74 available at: http://www.akleg.gov/basis/get_bill.asp?session=29&bill=sb++74, effective July 31, 2017.

[19] See, Pub. Act No. 17-115, available at: https://www.cga.ct.gov/2017/act/pa/pdf/2017PA-00115-R00HB-06012-PA.pdf. Conversely, Virginia explicitly authorized the practice of optometry and ophthalmology via telemedicine subject to certain conditions. See, Va. Code § 54.1-2400.01:2(B).

[20] See, 22 TAC 174.4 and 174.5.

[21] Tennessee's passage included a delayed implementation until 2019.

[22] States actively participating in the IMLC now include Alabama, Arizona, Colorado, Idaho, Illinois, Iowa, Kansas, Maine, Minnesota, Mississippi, Montana, Nebraska, Nevada, New Hampshire, Pennsylvania, South Dakota, Tennessee, Utah, Washington, West Virginia, Wisconsin and Wyoming.

[23] Telemedicine parity laws require insurers to cover services delivered via telemedicine to the same extent as coverage for the same service when delivered in-person. Parity laws may relate to coverage of the service or reimbursement of the service, or both, and may apply to the states' Medicaid programs, Medicaid managed care organizations, state employee health programs, or commercial payors operating in the state.

[24] Massachusetts and Rhode Island are the only two states without definitive reimbursement rules for telemedicine in their FFS Medicaid programs; however, Massachusetts Medicaid managed care plans may reimburse for telemedicine.

[25] See, 2017 Mercer National Survey of Employer-Sponsored Health Plans.

[26] In addition, two other bills impacting the Indian Health Services and the Veterans Administration were introduced this year. H.R. 1369 To Amend the Indian Health Care Improvement Act, was introduced to the U.S. House of Representatives to revise and extend the IHCIA. The bill established, among other things, the Indian Health Care Improvement Fund, which allows the secretary to disburse funds for various of reasons including, among others, the use of telemedicine when appropriate. The Veterans Community Care and Access Act of 2017, introduced in the Senate, seeks to modernize the VA by allowing licensed VA physicians to practice telemedicine across state lines regardless of where they are located. The bill would supersede state licensing restrictions and prohibit states from taking legal action against VA providers for

practicing telemedicine across state lines. Each of these bills aims to expand telemental health services to reduce suicide rates among the respective populations.

[27] See, https://www.congress.gov/bill/115th-congress/senate-bill/870.

[28] The cap has not been increased since 1996 despite the inclusion of skilled nursing facilities as a new class of provider.

[29] See, “Statement from FDA Commissioner Scott Gottlieb, M.D., on advancing new digital health policies to encourage innovation, bring efficiency and modernization to regulation” (Dec. 7, 2017), available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm587890.htm.

[30] Outlines the FDA’s approach to ensuring timely access to high-quality, safe and effective digital health products. The plan contained several key goals, including increasing the number and expertise of digital health staff at the FDA, launching a digital health software precertification pilot program, and issuing guidance to modernize FDA policies.

[31] Outlines the FDA’s approach to clinical decision support software (CDS). CDS has many uses, including helping providers, and ultimately patients, identify the most appropriate treatment plan for their disease or condition. This draft guidance is intended to make clear what types of CDS would no longer be defined as a medical device, and thus not regulated by the FDA.

[32] Outlines the FDA’s interpretation of the types of software that are no longer considered medical devices. Under this draft guidance certain digital health technologies, such as mobile apps that are intended only for maintaining or encouraging a healthy lifestyle, generally fall outside the scope of the FDA’s regulation.

[33] Establishes common principles for regulators to use in evaluating the safety, effectiveness, and performance of Software as a Medical Device.

[34] The Ryan Haight Online Pharmacy Consumer Protection Act restricts providers from prescribing controlled substances to patients who have not received an in-person medical evaluation. It currently contains seven separate “practice of telemedicine” exceptions that do not account for current clinical telemedicine practices. To address these deficiencies, the Drug Enforcement Administration, which enforces the Ryan Haight Act, has announced plans for a special telemedicine registration provision which would allow providers to use telemedicine to prescribe controlled substances without an in-person exam. Despite an expected 2017 release date, however, the DEA has yet to promulgate a new rule.