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Telehealth Emerging Legal and Regulatory Issues: Adopting and Implementing Innovative Solutions

Navigating Standard of Care, Privacy and Security, FDA Regulation, Advertising, Reimbursement, and More

THURSDAY, NOVEMBER 5, 2020

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Telehealth Emerging Legal and Regulatory Issues: Adopting and Implementing Innovative Solutions

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November 5, 2020

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Overview of Today's Webinar

- Defining Telemedicine/The Digital Health Landscape
- Standard of Care/Licensure
- Reimbursement
- Risk and liability
- Accessibility

Overview of Today's Webinar

- Privacy and Security
- Direct-to-consumer advertising
- Telehealth and Other Digital Health Technologies
  - FDA Regulation of Digital Health Technologies
  - Remote Monitoring
  - Data Issues
- Best practices for adopting and implementing innovative telehealth solutions

Telehealth and Telemedicine: A Primer

- General definition
  - Use of electronic information and telecommunications technologies to support and promote long-distance clinical health care, patient and professional health-related education, and public health and health administration.
    - Technologies include videoconferencing, the internet, store- and-forward imaging, streaming media, and landline and wireless communications

- Missions of Telehealth and Telemedicine
  - Increased access to patients in rural or underserved areas
  - Expanded availability of specialists and consultants
  - Respond to COVID-19 “challenges”

Telehealth and Telemedicine: A Primer

- Basic terminology and application
  - Telehealth → overall access to health information
    - Exchange of patient information
    - Health-related education
    - Public health / health care administration data
    - Clinical health care
  - Telemedicine → individual patient care
  - Distant site → location of practitioner
  - Originating site → location of patient

Telehealth Modalities

- **Synchronous**: Care provided in real-time, either by telephone or live audio-video interaction, typically with patient using a smartphone, tablet, or computer.
  - In some cases, peripheral medical equipment (e.g., digital stethoscopes, otoscopes, ultrasounds) can be used by another HCP (e.g., nurse, medical assistant) physically with the patient, while the consulting medical provider conducts a remote evaluation.
- **Asynchronous:** Care provided via “store and forward” technology where messages, images, or data are collected at one time, then addressed at later time.
  - Patient portals can facilitate this type of communication between provider and patient through secure messaging.
- **Remote patient monitoring:** Allows direct transmission of patient’s clinical measurements from a distance to their healthcare provider.
  - Can occur either in real-time, or via store and forward technology.

Standard of Care: Licensure and the Practice of Interstate Telemedicine

- Licensing requirements
  - No national license to practice medicine in U.S.A.
  - Health care practice/licensure traditionally monitored and regulated by individual states
  - Under normal circumstances, telemedicine providers typically needed to be licensed at originating site
    - If provider is located in Arizona, but the patient is located in Maine, the provider must have a valid license in Maine
    - Implications regarding logistics, efficiency, cost, etc.

Licensure through the Interstate Medical Licensure Compact (“IMLC”)

- General overview
  - Facilitates physician licensure in multiple states without the need to apply individually to each state
  - Primary mission is to “increase access to health care for patients in underserved or rural areas and allowing them to more easily connect with medical experts through the use of telemedicine technologies.”
  - IMLC “strengthens public protection by enhancing the ability of states to share investigative and disciplinary information.”

Licensure through the Interstate Medical Licensure Compact ("IMLC")

- How it works
  - Physician obtains license at their principal location (State Principal License "SPL")
  - Physician applies for licensure through "The Compact"
    - Requests licensing board at SPL to verify information and conduct background check
  - Physician selects state to practice
  - Approximately 80% of physicians already meet criteria for licensure through IMLC
  - IMLC currently exists among twenty nine states, along with Dist. of Columbia and Guam

Licensure Accommodations for COVID-19

- Relaxation of licensure requirements as part of COVID-19 response
  - 1135 waivers allow practitioners to bypass licensure requirements
    - Must be enrolled in the Medicare program
    - Must possess a valid license to practice in the state pertaining to their Medicare enrollment
    - Must be furnishing professional services – whether in person or via telehealth – in a state in which the emergency is occurring in order to contribute to relief efforts
    - Must not be affirmatively excluded from practice in the state or any other state that is part of the 1135 emergency area

Licensure Accommodations for COVID-19

- Guidance to States from Department of Health and Human Services (March 13, 2020)
  - Temporary waiver of licensing requirements for health care providers
- Many states have implemented licensure waivers during COVID-19 emergency
  - Specifics of waiver depend on state
    - Full licensure waiver
    - Expedited licensure
    - Provisionary licensure for treatment of new patients are limited to COVID-19 diagnosis and treatment
- Waivers are time-sensitive

Standard of care: Case law update

- Verdicts and Outcomes
  - Open issue → few cases address negligence principles with provision of telemedicine
  - In some states, the provision of care via telemedicine is not prohibited, but it is not statutorily regulated.
  - Individual state legislation regarding telemedicine is expected to increase theories of informed consent, negligence and negligence *per se*

Standard of care: Case law update

- *Smith, et al. v. Kaiser Foundation Hospitals,* 2020 WL 5064282 (S. D. CA. August 26, 2020)
- *Berman v. Innovative Speech & Language Pathology*, 2020 WL 4669618 (Cal. Super. August 10, 2020)
- *American College of Obstetricians & Gynecologists, et al. v. U.S. Food & Drug Administration, et* al., 2020 WL 3960625 (U.S. Dist. Maryland July 13, 2020)
- Moghtader *v. Geo Grp., Inc.*, 2020 U.S. Dist. LEXIS 56636 (March 31, 2020), *prior history* 2019 U.S. Dist. LEXIS 103223 (W.D. Tex., June 20, 2019)

Standard of care: Case law update

- *Bishop v. Wexford Health Sources, Inc*., 2019 U.S. Dist. LEXIS 203919 (W.D. PA. Nov. 25, 2019)

- *Jones v. Tritt,* 2019 U.S. Dist. LEXIS 26301 (W. D. PA. February 20, 2019)

- *Crawford v. Washington*, 2018 U.S. Dist. LEXIS 122566 (W. D. PA, June 11, 2018)

Sources of Authority Regarding Standard of Care

- State telehealth statutes
  - Regulate telehealth medical services
  - Set licensing standards
  - Provide directives regarding informed consent
  - Set forth requirements regarding documentation
  - Provide guidance regarding standard of care
    - Same as in-person treatment
    - If telehealth prohibits adherence to standard of care, must refer for in-person visit
- Other sources of authority may include state agency/executive publications

Reimbursement

- The basics
  - Who is the Payor? (federal and state payors may make reimbursement structures permanent, but commercial payors have been adjusting reimbursement to pre-PHE)
  - Who is the Provider?

- What are the pitfalls?
  - Confirm that services being provided via telemedicine are covered
  - Compensation must be consistent with Fair Market Value (FMV) involving commercially reasonable terms
  - Lack of parity
  - Fraud and abuse considerations
  - Lost revenue for services that cannot be provided via telehealth

Reimbursement

- Impact of the telehealth explosion as a result of COVID-19 pandemic
  - Expansion of telehealth services in state Medicaid programs
    - CMS guidance provides states with "broad flexibility" to *cover* telehealth services, including the "methods of communication . . . ."
      - Telephonic, video technology commonly available on smart phones and other devices
    - "No federal approval is needed for state Medicaid programs to *reimburse* providers for telehealth services in the same manner or at the same rate that states pay for face-to-face services."
  - Parity
    - Payment parity: Requires insurers to reimburse/pay at same rate
    - Service/coverage parity: Requires insurers to provide same level of coverage

Reimbursement

- Expansion of coverage and reimbursement for telehealth services in private plans, equal to in-person care
  - Parity arrangements traditionally differ by state – traditionally, service parity is more common than payment parity
  - Many states have mandated *service and payment* parity requirements for private plans
- Elimination of cost-sharing/waiver of co-pays
- Positive and negative implications of parity

Risk and Liability: Impact of COVID-19

- Prevalence of negative outcomes related to COVID-19 increases propensity for litigation

- Many states have passed laws/issued orders granting immunity to health care providers
  - Rationale
    - Treatment for disease still not well understood
    - Treatment provided outside physician's specialty area
    - Limited supplies (testing, ventilators)

Risk and Liability: Impact of COVID-19

- Issues to keep in mind regarding COVID-19 immunity
  - Limitations on treatment provided
    - Requirements regarding COVID-19 related treatment
  - Limitations on type of provider
    - Individual vs. facility
  - Limitations on time
    - Existence of retroactive date
    - Dependency on “public health emergency status”
  - Limitations on conduct
    - Willful/reckless conduct
    - Gross negligence
  - Nature of legal protections vary by state
    - Law/legislation vs. executive order

Risk and Liability: Impact of COVID-19

- Immunity for volunteer services
  - CARES Act – immunity for health care professionals providing volunteer services as a response to COVID-19 emergency
    - Exception for gross negligence, recklessness, or willful misconduct
    - Treatment must be within scope of physician's practice
  - Volunteer Protection Act of 1997 – liability protections to uncompensated medical volunteers who perform services for nonprofits or government entities
    - Treatment must be within scope of physician's practice

Risk and Liability: Impact of COVID-19

- Immunity – PREP Act
  - Authorizes HHS Secretary to issue declarations providing immunity for actions related to pandemic response measures
  - March 17, 2020 HHS Declaration providing immunity for “qualified persons” (licensed health professionals) who administer/prescribe “countermeasures” to treat COVID-19
    - “Countermeasures” = antiviral medications, other drugs, biologics, vaccines, diagnostics and/or devices (e.g., COVID-19 testing and respiratory therapy)
      - Premarket approval is required
      - Must be qualified pandemic or epidemic products, security countermeasures, or drugs, biologics, or devices authorized for emergency or investigational use

Risk and Liability: Impact of Venue

- Limited to no guidance regarding telemedicine
- COVID-19 emergency presents novel circumstances regarding venue and telemedicine
  - Likelihood of venue at distant originating sites (foreign states)
- Possible remedy → “forum selection clause” with initial patient agreement

Accessibility: Waivers and Other Measures

- CMS waivers found at: https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers
- Removal of traditional boundaries to health care delivery during COVID-19 crisis
- 1135 Waivers
  - Issued pursuant to Section 1135 of Social Security Act
  - Increase access to medical services during national emergency by allowing waiver of administrative requirements under federal law
  - Requires declaration of public health emergency by HHS Secretary (January 31, 2020)
  - Requires Presidential declaration of emergency (March 13, 2020)

Accessibility: Waivers and Other Measures

- Blanket waivers issued for “similarly situated providers”
- 1135 Waivers regarding Telehealth and Telemedicine: https://www.cms.gov/Medicare/Medicare-general-information/telehealth/telehealth-codes
- CMS categorizes telehealth as a method of care delivery and not a unique medical service
- Removal of originating site facility / geographic restrictions, so the patient can be located anywhere (including the patient’s home) to receive service
- Distant site restrictions have been removed, with any Medicare-approved provider qualified to serve as a distant site. Provider may provide telehealth services from provider’s home.

Accessibility: Waivers and Other Measures

- Interactive apps with audio and visual capabilities may be used to provide telemedicine care.
- Currently over 80 additional services may be provided via telemedicine, and process of adding services has changed. Formal rule-making process no longer required to add a telehealth service. Rather, CMS will add new telehealth services on a sub-regulatory basis, broadly considering specific requests from practitioners.
- Examples of waivers:
  - Audio-only telemedicine approved for parity in payment in specific circumstances (i.e. behavioral health and education services) (April 30, 2020)
  - Waive requirement for contract between hospital and telemedicine contractor
  - Remove Medicare coverage limitations - telehealth visits reimbursed at same rate as in-person visits
  - Enable state Medicaid expansion of telehealth services without further federal approval
  - Waive requirements for in-person visits for nursing home residents, dialysis patients, and home health patients (initial visits)
  - Waive requirements for prior physician-patient relationship
  - Waive requirements for emergency department screening of EMTALA patients
  - Waive licensure requirements under specific circumstances

Accessibility: Waivers and Other Measures

- Individual waivers – issued for specific states, providers, or suppliers
  - Requirements for waiver request
    - Detailed information about facility/practice
    - Short statement regarding justification for waiver
    - Consult capable legal counsel
    - Note relevant state and local laws
- CMS waivers (and flexibilities): https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers

Accessibility: Waivers and Other Measures

- Possible liability protections from 1135 waivers
  - Protections regarding tort law are limited
    - Waivers primarily pertain to administrative requirements
  - Limitations regarding administrative requirements/compliance
    - No authority to waive state law
    - Confined to duration of COVID-19 public health emergencies

Accessibility: Waivers and Other Measures

- Coronavirus Aid, Relief, and Economic Security (CARES) Act: 116 P.L. 136
  - Relaxation of requirements under Medicare statutes and regulations
    - HHS Secretary has authority to waive "requirements of Section 1834(m)"
  - Relaxation/waiver of requirements regarding in-person visits
    - Hospice
    - Dialysis
    - Veteran-directed care
  - Relaxation/waiver of requirements regarding location of originating site
    - Can now be at patient's home, rather than physician's office or health care facility

Accessibility: Waivers and Other Measures

- Expansion of remote patient monitoring availability in home health setting
- Increased funding for telehealth access and infrastructure
- Expanding scope of providers that may provide telehealth services
  - Expansion of inclusion criteria for distant site providers
    - Federally Qualified Health Centers
    - Rural Health Clinics

Accessibility:
Efforts to Permanently Expand Telehealth Waivers

- Executive Order 13941 of August 3, 2020 “Improving Rural Health and Telehealth Access”: President Trump required that, within 60 days, the Secretary of the Department of Health and Human Services would propose regulations to expand new telehealth practices beyond COVID-19 pandemic
  - Also requires HHS and the Department of Agriculture to work together to improve physical and communications infrastructure to expand Telehealth access in rural communities

- HEALTH Act of 2020 (U.S. House of Representatives effort from June, 2020): codify Medicare reimbursement, permanently remove originating site facility and location requirements for distant site telehealth services with FQHCs and RHCs

Accessibility:
Efforts to Permanently Expand Telehealth Waivers

- EACA (Equal Access to Care Act) (U.S. Senate effort from June, 2020): U.S. Senate proposes to permit licensed providers to provide telehealth services to any state, in any location for 180 after the end of the public health emergency period

- Continuing bipartisan efforts in the U.S. Senate to make two telehealth changes permanent: removing the originating site rule and expanding the scope of reimbursable services

Privacy and Security: Patient Protections under HIPAA

- Office for Civil Rights Notice of Enforcement Discretion (March 17, 2020)
  - Identifies platforms for telehealth services
    - Skype for Business / Microsoft Teams; Updox; Vsee; Zoom for Healthcare; Doxy.me; Google G Suite Hangouts Meet; Cisco Webex Meetings / Webex Teams; Amazon Chime; GoToMeeting; Spruce Health Care Messenger
  - Prohibits “public-facing” platforms
    - Only platforms that allow intended users are permitted

Privacy and Security: Patient Protections under HIPAA

- "Encourages" implementation of Business Associate Agreements with platforms used to provide telehealth services
- Waives sanctions for HIPAA violations during COVID-19 emergency, if activities pertain to "good faith" provision of telehealth services
  - "Enforcement discretion" applies to telehealth services provided for any reason, regardless of whether telehealth service is related to treatment of COVID-19

Privacy and Security: Patient Protections under HIPAA

- Office for Civil Rights Bulletin (March 17, 2020)
  - Privacy Rule provisions remain in place
  - Covered entities cannot disclose protected health information without authorization
  - Exceptions:
    - Reporting information to “public health authority”
    - Reporting information to “persons at risk”
    - Reporting information to family/friends “involved in the patient’s care”
      - Must be identified by the patient
    - Reporting information to “prevent or lessen a serious and imminent threat” to an individual or the public

Advertising Issues

- Know Federal and state laws before entering a market area
- American Telemedicine Association good resource: https://www.americantelemed.org/
- In-house marketing vs. outside marketing provider
- Have an executed BAA with outside vendors
- Advertising methods: website, emails, commercials (TV, internet and social media platforms), telehealth blogs

FDA Regulation of Telehealth Digital Technologies

- Relaxation of regulations in the setting of COVID-19
  - Pre-market certification regarding prescription-only connected health tools (apps and devices) designed to treat mental health condition
  - "Limited" modifications regarding indications, claims, functionality, or hardware/software of non-invasive remote patient monitoring devices
    - Use of "hospital-only" devices in home setting
    - Hardware/software chances to increase remote monitoring capability
- Adjustments to premarket review protocols for AI and machine learning-driven software modifications
  - "Predetermined change control plan"

Remote Patient Monitoring

- Remote patient monitoring devices collect, store and/or transmit data
- Mobile Medical Apps (MMAs)
  - Potentially create more than product liability issues
  - Increasingly used by patients & providers
  - Examples:
    - Monitoring & controlling → insulin pump delivery
    - Stethoscope function
    - Patient analysis → radiation dose, BMI, vital signs
    - Reference apps → drug interaction, drug allergy
    - Communication → access health records & other data
- Wearable Biosensors
- Smartphone applications

Remote Monitoring: FDA Digital Health Innovation Action Plan

- Redesigns & streamlines FDA review process for medical software
- FDA reimagining approach to digital health product oversight including medical devices
- FDA will develop precertification program that will allow decreased submission content & faster review
- FDA's Center for Devices & Radiological Health (CDRH) could "pre-certify" eligible digital health developers
  - July 2017 → FDA Commissioner Dr. Scott Gottlieb announces digital health app developer Pre-Cert Program
  - August 2017 → Pre-Cert pilot program opens

Data Issues: A General Overview

- Privacy: Is the data secure?
- Technology: Is the data accurate?
- Storage: Where is the data being stored? Performed within health care system or through outside vendor
- Commercialization of Data: Is the facility sharing / selling data in a way which comports with Federal, State and ethical requirements?

Telehealth, Data, and COVID-19: A Double-edged Sword

- Data privacy and security are critical components of telehealth services, but also present potential liabilities

- Prevalence of telehealth services during COVID-19 increases propensity for cyber-attacks
  - Rapid expansion of delivery models creates instability/new threats
    - Proliferation of patient-facing mobile apps
    - Cybersecurity measures must match surge in use
  - Relaxations in privacy/security requirements during COVID-19 emergency present additional vulnerabilities

What Can be Done to Address Challenges with Data?

- Priorities for telehealth security
  - Ensure transmission of treatment sessions utilizes secure technology/platform
  - Maintain “at rest” data to reduce breaches
    - Data encryption
    - End user (employee) training
    - Control of data access points (professional vs. personal equipment)
    - Compliance enforcement
    - Insider threat monitoring
  - Review vendor contracts for indemnity clause
  - Develop incident response plan in case of breaches

Suggested Telehealth Best Practices

- Documentation, documentation, documentation!
  - Maintain separate documentation
  - Patient's request for telemedicine services
  - Patient's consent to telemedicine services (including limitations of services and security limitations with telehealth platform)
  - Name and location of participants (patient, provider, medical assistants, family members – ensure that provider is licensed to provide care where the patient is located, and educate patients that care may be declined if the patient is in a location where the provider is not licensed)

Suggested Telehealth Best Practices

- Telemedicine platform used during visit (i.e.: audio only via telephone, audio / visual using Zoom for Healthcare)
- Synchronous vs. asynchronous
- Start and stop time for telemedicine visit
- Reason why visit was conducted via telemedicine with provider attestation that treatment via telemedicine was appropriate

Suggested Telehealth Best Practices

- Documentation issues regarding COVID-19
  - Pitfalls related to auto-populated data
  - Chronical technical issues now
  - Note relaxation(s) of documentation practices during pandemic
  - Detail expanded staff duties and privileges, if applicable
  - Accept and plan for deficiencies due to pandemic-related constraints
- Good faith efforts regarding privacy requirements
  - Limitations of “enforcement discretion”

Suggested Telehealth Best Practices

- Practice using technology with staff before providing treatment to patients
- Create backup plans
- Keep staff advised of policy or billing changes to maintain compliance
- Avoid long-range planning due to temporal limitations of COVID-19 emergency

Questions/comments?

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