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Challenges and opportunities of telemedicine and mhealth solutions

Thursday, February 9, 2017

Speakers

Lisa Genecov, *Head of Healthcare Transactions, Dallas*

With over 30 years of experience, Lisa Genecov has built a practice focused on providing legal services to the health care industry. She devotes her practice to the regulatory, business, corporate, governance, compliance, M&A and transactional aspects of health care law.

She advises clients on transaction structures, implementation matters, compliance obligations and strategic opportunities under the Affordable Care Act and related healthcare laws and regulations. She also regularly advises the boards of health care entities on governance issues.

Lisa counsels various hospitals and health systems, medical groups and other health care providers in both regulatory matters as well as business transactions, including: acquisitions and divestitures of hospitals, the development and formation of accountable care organizations, clinically integrated networks and physician/hospital/payor alignment strategies; physician and hospital contracting, physician employment and recruitment issues; physician practice management and management services agreements; corporate practice of medicine and fee splitting issues; as well as advising on fraud and abuse and Stark Law compliance, tax-exempt and antitrust issues, and licensure and CHOW matters.

Speakers

Mark Faccenda, *Partner*

Mark Faccenda is part of Norton Rose Fulbright's health care transactional group, Mark has represented health care industry clients on regulatory and transactional matters. Representative clients include pharmaceutical manufacturers, academic medical centers, health systems, physician groups, physician/hospital joint ventures, long-term care facilities and durable medical equipment suppliers.

Prior to joining, Mark worked for the Pennsylvania House of Representatives Legislative Office for Research Liaison where he conducted economic and health care regulatory research in support of prospective legislation. As part of his work for the Legislative Office for Research Liaison, Mark authored and contributed content to the University of Pittsburgh Institute of Politics' quarterly Institute of Politics Report and its annual policy briefing, the Institute of Politics Status Report.

Mark also worked for payer and provider sides of an integrated health system where he drafted corporate policies and provided legal research focusing on HIPAA, ERISA, EMTALA, same-sex benefit coverage and the Peer Review Protection Act.

Continuing Education Information

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- Today's program will be conducted in a listen-only mode. To ask an online question at any time throughout the program, click on the question mark icon located on the toolbar in the bottom right side of your screen. Time permitting, we will answer your question during the session.
- Everything we say today is opinion. We are not dispensing legal advice, and listening does not establish an attorney-client relationship. This discussion is off the record. You may not quote the speakers without our express written permission. If the press is listening, you may contact us, and we may be able to speak on the record.

Considerations for Developing a Telemedicine Program

- What is Telehealth, Telemedicine, mhealth/mobile health?
- Standard of Care -- Establishing the Physician-Patient Relationship
- Corporate Practice of Medicine
- Types of Arrangements and Business Considerations
- Teledoc Case

Definitions

TELEHEALTH

Telehealth is defined as the use of telecommunications and information technologies to share information, and provide clinical care, education, public health, and administrative services at a distance.[1]

Telemedicine

"The practice of medicine using electronic communication, information technology or other means between licensee in one location, and a patient in another location with or without an intervening healthcare provider."[2]

Examples of services: PC and specialist referral services; remote patient monitoring.[3]

Examples of delivery mechanisms: networks between healthcare centers; point-to-point connections between healthcare centers and independent providers; monitoring center links; web-based e-health patient service sites.[4]

mHealth

"mHealth is the use of mobile and wireless devices to improve health outcomes, healthcare services and health research."[5]

Rules for Practicing Interstate Telemedicine

California	A practitioner [not licensed in CA] shall not open an office, appoint a place to meet patients, receive calls from patients within the limits of this state, give orders, or have ultimate authority over the care or primary diagnosis of a patient who is located within the state. Does not apply to any practitioner located outside this state, when in actual consultation, whether within this state or across state lines, with a licensed practitioner of this state. Cal. Bus. & Prof. Code § 2060
New York	Any physician who is licensed in a bordering state and who resides near a border of this state, provided such practice is limited in this state to the vicinity of such border and provided such physician does not maintain an office or place to meet patients or receive calls within this state is exempt from licensure. Consultation also permitted without licensure. N.Y. Educ. Law § 6522
Texas	A person who is physically located in another jurisdiction but who, through the use of any medium, including an electronic medium, performs an act that is part of a patient care service initiated in this state, including the taking of an x-ray examination or the preparation of pathological material for examination, and that would affect the diagnosis or treatment of the patient, is considered to be engaged in the practice of medicine in this state and is subject to appropriate regulation by the board. Episodic consultation permitted without licensure. Tex. Occ. Code Ann. § 151.056

Some States Provide for Telemedicine Licensure or Registration

- Several states offer a conditional registration or telemedicine license to out of state physicians in lieu of full licensure to practice in the state.
- Generally, the listed licenses or registrations to practice telemedicine require the provider to 1) hold a full license to practice in another state, 2) not open an office or meet with patients in person in the state, and 3) submit to jurisdiction and compliance with the laws of the state providing the license or registration.

Some States Provide for Telemedicine Licensure of Registration *(Cont'd)*

- Texas provides for a limited license that allows a physician to practice medicine across state lines. An Out-of-State Telemedicine License holder is not authorized to physically practice medicine in the State of Texas.
  - **The license holder's practice of medicine under this license is limited exclusively**: to the interpretation of diagnostic testing and reporting of results to a Texas fully licensed physician practicing in Texas; or, for the follow up of patients where the majority of patient care was rendered in another state.
  - The holder of an Out-of-State Telemedicine License is subject to the Medical Practice Act and the same Rules of the Board as a person holding a full Texas medical license, which includes paying the same fees and meeting all other requirements (such as CME) for issuance and renewal of the license as a person holding a full Texas medical license.

3 General Categories or Types of Telemedicine Care

- Real-Time Care
  - Live audio/video conferencing between provider and patient
  - Patient presents at originating site and is connected synchronously with a provider at another site
- “Store and Forward”
  - Digital data (images, records, audio/video, etc.) that are captured and transmitted to a provider for further study or second opinions
  - Typically seen with diagnostic interpretations
- Remote Monitoring
  - Monitoring equipment transmits patient data to healthcare professionals (chronic care management, diabetes, cardiac care, etc.)

Elements of Physician-Patient Relationship

Evaluation that meets applicable “Standard of Care”

- Identify patient
- Gather information

Informed Consent

- Patients should receive information necessary to make a meaningful decision about their medical care and treatment

Diagnosis

- Physician’s discretion to collect necessary information

Treatment

- Prescription of medicine

Follow-up care

- Ensure availability of follow up care by a physician located in patient’s state
- Establish an emergency situation referral plan

Documentation

- Confidentiality/EHR Requirements
- Maintain patients’ medical records and make available to both patients and patient’s health care providers

Continuous care

- Mostly prohibited through telemedicine (generally, for out of state physicians)

Standard of Care:
Establishing the Physician-Patient Relationship

- General Definition: "The reasonable and customary conduct demonstrating minimal competence under the circumstances"
- Telemedicine laws:
  - Certain states allow physicians' discretion to conduct patient evaluations electronically
  - Other states require intermediary assistant where the patient is located
  - And other states require an in-person evaluation take place first before treatment through telemedicine:
    - For example, Texas Administrative Code section 190.8(L)(i)(c): "A defined physician-patient relationship must include, at a minimum: …physical examination that must be performed by either face-to-face visit or in-person evaluation…"
- Under most state laws, an audio-only encounter does not meet the standard of care for diagnosis or prescribing.

E-Prescribing Authority

- Prescribing authority depends on being able to establish a patient-physician relationship
  - In Texas, the prescription of any dangerous drug or controlled substance may not occur without first establishing a "defined physician-patient relationship," which includes a physical examination that must be performed by either a face-to-face visit or in person evaluation. For telemedicine purposes this includes a patient site presenter with the patient at an established medical site to assist the distant site provider with the internal in-person evaluation.

Case Study: Teladoc, Inc.

- Teladoc Inc.
  - Company that allows users to create an online profile, to upload medical records, and request a telemedicine consultation with a physician, including treatment by prescribing medicine
- Texas Medical Board (TMB)
  - April 10, 2015 adopted revised T.A.C. § 190.8(1)(L) that now requires a face-to-face examination for a physician to prescribe medicine to a patient

Teladoc, Inc., et al v. Texas Medical Board et. al

Teladoc sued TMB to enjoin it from implementing the newly revised Section 190.8(1)(L), arguing:

- TMB is not immune from antitrust suits because "state licensing boards made up of active members of the licensed profession are not immune from the antitrust laws when they take anticompetitive actions without the active supervision of the State." *N. Carolina Board of Dental Examiners v. FTC*
- TMB had not objected to on-call physicians treating patients they have never physically examined by phone and that there is no evidence that the telehealth services Teladoc had provided were not up to standard.
- TMB did not object to Teladoc's telehealth services until its business started to grow exponentially in 2009 and significantly competing with the traditional physician offices; the new rule would put Teladoc out of business in Texas, and have a detrimental effect on Teladoc nationwide.

TMB is concerned for public safety

- The revision to section 190.8(1)(L) is based on TMB's concerns for public safety, to maintain the quality standard of health care services in Texas.
- TMB is entitled to take (and has taken) disciplinary action against physicians who fail to "practice medicine in an acceptable professional manner consistent with public health and welfare."

Examples of Types of Agreements

- Telemedicine Services Agreement
- Credentialing and Privileging Agreement
- Equipment Agreement
- Technology or Software Licensing Agreement
- Business Associate Agreement
- Management Services Agreement

Corporate Practice of Medicine

- A non-physician person, partnership, association or corporation is prohibited from directly or indirectly engaging in the practice of medicine.
- Typical contractual structures used to comply with the corporate practice of medicine doctrine is through management or administrative services arrangements, professional services agreements or telemedicine/vendor platforms

Corporate Practice of Medicine

Texas

- **General corporate employment of physicians is prohibited in Texas.**
- Texas law prohibits, directly or indirectly, aiding or abetting, the practice of medicine by a person, partnership, association, or corporation that is not licensed to practice medicine by the Texas Medical Board. This provision has been interpreted generally as prohibiting a corporation (that is not a professional entity owned by physicians) from practicing medicine or employing a physician to practice medicine where the corporation (unlicensed person) collects the professional fees generated. Tex. Occ. Code § 164.052.

New York

- **General corporate employment of physicians is prohibited in New York.**
- Corporations are prohibited from hiring physicians save for certain exceptions, which include nonprofit corporations and hospital service corporations organized under insurance law; professional service limited liability companies; professional service corporations and hospitals within the scope of an operating certificate. N.Y. Educ. Law § 6527

California

- **General corporate employment of physicians is prohibited in California.**
- The California Supreme Court has recognized a "long-standing 'policy . . . against [the] corporate practice of the learned professions.'" *People v. Cole*, 135 P.3d 669, 672 (Cal. 2006). "For-profit corporations 'may not engage in the practice of ... medicine.'" *Id*. (citing *People v. Pacific Health Corp*. 82 P.2d 429 (Cal. 1938)). This ban on the corporate practice of medicine "generally precludes for-profit corporations--other than licensed medical corporations--from providing medical care through either salaried employees or independent contractors." *Id*.

Contracts with Telemedicine Technology Vendors – Key Issues

- Protect against liability for equipment failure.
- Specify technical specifications and interoperability standards.
- Ensure appropriate secure communication channels are in place.
- Ensure access to continued support services and technology updates.
- Have vendor represent and warrant technology's compliance with regulatory requirements.
- Determine what actions may be taken if contracted service requirements are not met (e.g., termination, indemnification, etc.).
- Include a Business Associate Agreement.
- Consider protective provisions for IP.
- Cyber liability insurance.
- Limitation of Liability Clauses.

Professional (Provider) Services Agreements – Key Issues

A. Throughout the term of agreement, each physician providing telemedicine services to Hospital shall:

- Comply with all applicable medical staff qualification requirements
- Maintain current unrestricted license to practice in the state
- Comply with Hospital's policies
- Remain a member in good standing in the practice/telemedicine entity
- Maintain a current, unrestricted federal and state controlled substances registration
- Maintain Medicare and Medicaid Provider Numbers
- Maintain all other licenses and certificates as Hospital may reasonably require
- Maintain malpractice coverage (specifically covering telemedicine services) in amounts specified (e.g., $1 million per occurrence and $3 million in aggregate)

Professional (Provider) Services Agreements *(Cont'd)*

B. Physician Scheduling
   - Maintain Exhibit List of Scheduled Physicians
   - Specify Coverage of practice/telemedicine entity (e.g. 24/7 coverage)
   - Allow Hospital to require removal of physician from list (for reasons not requiring a hearing – e.g., non-performance of specified requirements or qualifications)

C. Covenants Not to Compete
   - Must be reasonable as to Time, Place and Geographic Scope
   - Should comply with Section 15.50(b) of Texas Business and Commerce Code, including providing for a reasonable buy-out
   - Confidentiality of Proprietary Information

D. Address Use of Equipment and Space, if applicable (e.g., AKS)

Professional (Provider) Services Agreements *(Cont'd)*

E. Clearly set out provision of services and responsibilities of parties

F. Maintenance of medical records, access and confidentiality of records

G. No referrals; Billing and Collections

H. FMV for services

I. Term and termination; Breach and Cure

J. Representations and Warranties

K. Indemnification

Credentialing and Privileging

- States typically require licensed health care facilities to credential all individuals providing professional medical services at the facility
- Government and commercial payors also typically require health care facilities or provider organizations to credential all practitioners as a condition of participation
- A provider needs to be credentialed at both the originating site ***and*** the distant site

Credentialing by Proxy

- CMS adopted a process to allow for credentialing by proxy
  - Originating site may rely on distant site's prior credentialing of the provider
- Requires an agreement between both the distant site and originating site facilities that contains ongoing reporting requirements by the originating site facility on outcomes data

Credentialing by Proxy – Practical Implications

- Benefits:
  - Streamlines administrative process
  - Saves time
  - Saves money
- Originating site hospitals should review their medical staff bylaws, policies and procedures related to credentialing and privileging to comply with conditions of participation

Credentialing and Privileging Agreement

- CMS Telemedicine Rule (42 CFS Section 482.12(a)(8)-(9); 485.616(c)(2)(4)
- To rely on a distant-site hospital's credentialing and privileging decisions, the hospital or CAH must have a written agreement that establishes the following:

1. The distant-site hospital is a Medicare-participating hospital.
2. The distant-site practitioner is privileged at the distant-site hospital as evidenced by a current list of the practitioner's privileges provided by the distant-site hospital.
3. The practitioner holds a license issued or recognized by the state in which the hospital or CAH whose patients are receiving telemedicine services is located.
4. The hospital that credentials and privileges the distant-site practitioner shares the practitioner's performance review information with the distant-site hospital
   (42 CFR §§482.22(a)(3); 485.616(c)(2))

Credentialing and Privileging Agreement (Cont'd)

- To rely on the credentialing and privileging decisions by a **distant-site telemedicine entity**, the hospital or CAH **must have a written agreement** that establishes the following:
  1. The entity's process and standards for assessing the qualifications of its practitioners at least meet those standards set forth in the CoPs.
  2. The distant-site practitioner has the experience and expertise as represented by the distant-site telemedicine entity.
  3. The practitioner holds a license issued or recognized by the state in which the hospital or CAH is located.
  4. The hospital that credentials and privileges the distant-site practitioner shares the practitioner's performance review information with the distant-site entity.

  (42 CFR §§482.22(a)(4); 485.616(c)(4))

Required Provisions Under CMS' Telemedicine Rule: Monitoring Performance

- Hospitals **<u>are required</u>** to monitor distant-site telemedicine practitioners.
- Hospitals using telemedicine services of distant-site practitioners must maintain evidence of an internal review of the distant-site practitioner's performance of privileges and *send information to the distant site* for use in the periodic appraisal of the practitioner.
- The law requires, at a minimum, that the monitored and shared information include:
  - All adverse events that result from telemedicine services provided by practitioner to patients, and
  - All complaints the hospital has received about the practitioner (42 CFR §482.22(a)(3)(iv), (a)(4)(iv))

Legal Challenges and Barriers Affect Reimbursement

- Medicaid
- Medicare
- Private Payors

Table 2. Reasons for Not Billing for Services Delivered via Telemedicine

REASON	%	NUMBER
Practice in urban area	19.3	62
No Medicaid reimbursement	33.0	106
Major payers do not pay	32.4	104
Could not get support from my organization	4.7	15
Too risky for penalties for fraud and abuse	4.7	15
Services are bundled through contracts	17.4	56
Other	43.9	141

Medicare Reimbursement for Telemedicine Services

- Location of patient (originating site) must be:
  - outside a Metropolitan Statistical Area (MSA) or in a rural census tract
  - limited to certain facilities, including physician offices, hospitals, CAHs, RHCs, FQHCs, hospital-based ESRD, SNFs
- Medicare covers only telemedicine services using synchronous, interactive telecommunications systems
  - includes real-time video and audio interaction between the healthcare provider at the distant site and the patient at the originating site
  - excludes most store-and-forward applications

Medicare Reimbursement for Telemedicine Services

- Eligible provider types include physicians, PAs, NPs, nurse-midwives, clinical nurse specialists, clinical psychologists, clinical social workers, registered dietitians or nutrition professionals
  - state licensing, credentialing and privileging requirements apply (ordinarily at the originating site)
- Eligible type of services include office or other outpatient visits, professional consults, psychotherapy, pharmacology, transitional care management and alcohol and other substance abuse counseling and treatment.

Medicare – Remote Chronic Care Coordination Program

- Must be furnished using an electronic health record or other health IT or health information exchange platform
- Medicare provides a monthly fee ($40) to manage and coordinate the care of patients with two or more chronic conditions that are expected to last at least 12 months
- Non-face-to-face communication - telephone, secure messaging and email is allowed

Medicare – Remote Chronic Care Coordination Program

- CMS estimated that 100,000 reimbursement requests were submitted although nearly 35 million Medicare beneficiaries were likely to qualify
- Reasons for the low physician participation included insufficient guidance on proper coding and billing and challenges to navigate through the lengthy process on EHR systems
- CMS expects to raise interest in the program

Medicaid Reimbursement for Telemedicine

- Federal Medicaid statute does not recognize telemedicine as a distinct service
- States may determine:
  - whether or not telehealth services are covered,
  - what services are covered in what geographic areas,
  - which practitioners are reimbursed, and
  - how much services are reimbursed
- Differs from state to state, though the states must still satisfy the federal requirements of efficiency, economy and quality of care

Medicaid Reimbursement – State Survey (July 2015)

- 47 state Medicaid programs and DC are now reimbursing for live video telehealth
- 9 state Medicaid programs offer some reimbursement for store-and-forward, not counting states that only reimbursed for teleradiology
- 16 state Medicaid programs reimburse for remote patient monitoring
- 29 state Medicaid programs provide for a transmission or facility fee for telemedicine services
- 27 states require a telemedicine-specific informed consent be obtained from the patient

Private Payors

- Some health insurance companies partner with telemedicine service companies
- State Parity Legislation – payors may not distinguish between coverage for in-person services and telemedicine services
  - Denial of payment is higher for telemedicine services than in-person services
- According to the American Telemedicine Association, twenty-nine states and D.C. require parity and eight states have proposed parity legislation

CONNECT for Health Act

- Creating Opportunities Now for Necessary and Effective Care Technologies (CONNECT) for Health Act
  - "Bridge" Demonstration Waiver program consistent with the MACRA MIPS program
    - Program participants would not be subject to the Medicare payment limitations on site or technology
  - Extended demonstration waivers to qualifying alternative payment models (APM) participants
    - data reporting obligations under both waiver program and APM model
- Expands originating sites to include ESRD facilities, facilities where stroke evaluation or management services are provided via telehealth, Indian Health Service facilities
- Distant sites expanded to include RHCs and FQHCs

CONNECT for Health Act

- Improved Medicare coverage for remote patient monitoring services
  - available for patients:
    - with 2 or more Medicare-covered chronic conditions
    - at least 2 inpatient or ER visits in previous year
  - reimbursement available for renewable 90-day periods of remote patient monitoring
- Permits Medicare Advantage plans to use telehealth or remote patient monitoring services to provide benefits under the original Medicare fee for-service program option.
  - includes items or services furnished to treat medical or behavioral health conditions

Expanding Capacity for Health Outcomes (ECHO) Act

- HHS is instructed to examine technology-enabled collaborative learning and capacity building models and their impact on:
  - addressing mental and substance use disorders, chronic diseases and conditions, prenatal and maternal health, pediatric care, pain management, and palliative care;
  - addressing health care workforce issues, specialty care shortages, primary care workforce recruitment, retention, and training;
  - the implementation of infectious disease and public health surveillance programs;
  - the delivery of health care services in rural areas, HPSAs and MUAs, and to medically underserved populations and Native Americans

Expanding Capacity for Health Outcomes (ECHO) Act

- The ECHO Act sponsors the analysis of:
  - the use and integration of technology-enabled collaborative learning and capacity building models by health care providers;
  - the impact of models on health care provider retention;
  - the impact of models on the quality of, and access to, care for patients;
  - the barriers faced by health care providers, States, and communities in adopting models;
  - the impact of models on the ability of local health care providers and specialists to practice to the full extent of their education, training, and licensure, including the effects on patient wait times for specialty care; and
  - efficient and effective practices used by communities that have adopted models, including potential cost-effectiveness

General Healthcare Regulations Also Applicable

- Although many states have telemedicine-specific laws, it is important to keep in mind that telemedicine providers must still follow established regulations pertaining to healthcare, including:
  - Fraud and Abuse
  - Privacy and Security Regulations

Fraud & Abuse Considerations

- Anti-kickback: equipment exchange between providers
  - OIG evaluated telemedicine-specific models in 1998, 1999, 2004 and 2011, which focused on the value of the most often free consultative telemedicine services to both the referring and consulting practitioners, and evaluated any equipment exchange arrangements to determine inducement of referrals
  - June 2015 OIG Fraud Alert on Physician Compensation Arrangements
- Stark Law
  - New exception for timeshare arrangements (42 CFR 411.357(y))
  - In-office ancillary services exception (42 CFR 411.355(b)) issues

FDA Jurisdiction– Mobile Apps

FDA's regulatory oversight is limited to apps that are intended to perform medical device functions:

Intended to be used as an accessory to a regulated medical device; or

- *e.g.*, Mobile apps that control the inflation or deflation of a blood-pressure cuff.

Intended to transform a mobile platform into a regulated medical device.

- *e.g.*, Mobile apps that use a sensor or lead that is connected to a mobile platform to measure and display the electrical signal produced by the heart (electrocardiograph or ECG).

Is a Mobile App a Medical Device?

- **The intended use of a mobile app determines whether it meets the definition of a "device."**
- If the intended use of the mobile app is for the diagnosis of disease or other conditions; or the cure, mitigation, treatment, or prevention of disease; or is intended to affect the structure or any function of the body of man, it is subject to FDA regulations.
- Intended use may be shown by labeling claims, advertising materials, or oral or written statements by manufacturers or their representative. *See* 21 CFR 801.4.

Is a Mobile App a Medical Device?

- FDA regulates mobile apps that are medical devices.
- FDA exercises “enforcement discretion” on mobile medical apps that are not devices due to a perceived low risk to patients.
- Under enforcement discretion, FDA retains the right to enforce applicable FDCA requirements, but FDA has declined to do so at this time.

Is a Mobile App a Medical Device? Examples

Mobile Apps FDA DOES NOT regulate

- Electronic copies of medical textbooks and other reference materials
- Educational tools for medical training
- Patient education
- Automated general office operations, not intended for diagnosis, cure, mitigation, treatment or prevention of disease (*e.g.*, used in determining billing codes, analyzing insurance claims for fraud and abuse, managing shifts for practitioners)
- Generic aids or for general purpose (*e.g.*, mobile platforms that allow health care providers to communicate in a secure and protected method)

Mobile Apps FDA MAY regulate

- Apps intended to help patients (*i.e.*, users) self-manage disease or conditions without providing specific treatment or treatment suggestions (*e.g.*, inhaler usage tracker);
- Provide patients with simple tools to organize and track their health information (*e.g.*, weight trend tracking);
- Provide access to information related to patients' health conditions or treatments (*e.g.*, drug-drug interaction compendium);
- Help patients document, show, or communicate potential medical conditions to health care providers;
- Automate simple calculations for health care providers;
- Enable patients or providers to interact with Personal Health Record (PHR) or Electronic Health Record (EHR) systems; or
- Medical Device Data Systems (MDDS) intended to transfer, store, convert format, and display medical device data in its original format from a medical device.

Mobile Apps FDA DOES regulate

- Apps used as an extension of a medical device for controlling the device or for use in active patient monitoring or analyzing medical device data (*e.g.*, blood pressure cuff controller);
- Apps that transform mobile platform into medical device by including functionalities similar to those of currently regulated medical devices (*e.g.*, use of glucose strip reader attachment to function as a glucose meter);
- Apps that perform patient-specific analysis or provide patient-specific diagnosis (*e.g.*, dosage calculators);

Requirements for Medical Device Manufacturers

- Annual registration of facilities
- Disclosure of devices marketed
- Compliance with branding / labeling regulations
- Filing of appropriate premarket submissions w/ FDA
- Correction of FDA-identified device problems

Secure Text Messaging

- Text messaging – Joint Commission ban lifted:
  - "Licensed independent practitioners or other practitioners in accordance with professional standards of practice, law and regulation, and policies and procedures may text orders as long as a secure text messaging platform is used and the required components of an order are included."
- Secure text messaging platform requirements:
  - Secure sign-on process
  - Encrypted messaging
  - Delivery and read receipts
  - Date and time stamp
  - Customized message retention time frames
  - Specified contact list for individuals authorized to receive and record orders
- HIPAA informal guidance – all unencrypted transmissions are breaches of ePHI

Cybersecurity Implications for Medical Mobile Apps

Any device that uses software and connects to a healthcare network introduces risk

- FDA recommends that manufacturers apply the NIST Framework for Improving Critical Infrastructure Cybersecurity: Identify, Protect, Detect, Respond and Recover
- FDA recommends that manufacturers and companies implement comprehensive cybersecurity risk management programs and quality management systems consistent with 21 CFR part 820

Addressing cybersecurity exploits:

- "For the majority of cases, actions taken by manufacturers to address cybersecurity vulnerabilities and exploits are considered "cybersecurity routine updates or patches," for which the FDA does not require advance notification or reporting under 21 CFR part 806."
- "For a small subset of cybersecurity vulnerabilities and exploits that may compromise the essential clinical performance of a device and present a reasonable probability of serious adverse health consequences or death, the FDA would require medical device manufacturers to notify the Agency."

Other Issues – Reasonable Security Measures

- Merge Hemo device interruption
  - During cardiac catheterization resulting from a routinely scheduled antimalware scan
  - Security controls should not unreasonably hinder access to a device that is typically used in emergency situations
  - FDA also urged manufactures to carefully consider the balance between cybersecurity safeguards and the usability of the device in its intended environment of use.
- Ransomware – Hollywood Presbyterian Medical Center
  - May be coming to mobile applications soon
  - Defend against the initial intrusion
  - Monitor, detect and block
  - Backup, restore and lockout under business continuity and disaster recovery plan

Resources for Mobile App Developers

- HHS guidance (mHealth Developer Portal) providing scenarios where HIPAA regulations might apply to mobile health applications
  - http://HIPAAQsportal.hhs.gov
  - How does HIPAA apply to health information that a patient creates, manages or organizes through the use of a health app?
  - When might an app developer need to comply with the HIPAA Rules?
    - Does the app receive, maintain or transmit PHI on behalf of a covered entity? If so, HIPAA would apply.
    - Does the app permit patient management services, remote patient health counseling, monitoring of patients' food and exercise, patient messaging, EHR integration and application interfaces? If so, HIPAA would likely apply.
- FTC guidance for mobile app developers
  - Intended to provide a resource re: applicable federal laws and regulations on advertising and marketing, medical devices, and data security and privacy for personal health records
  - https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-apps-interactive-tool?utm_source=govdelivery

Key Take Aways

- Stay current on legal/regulatory updates:
  - States licensing and standards of care
  - New states and federal regulations related to telehealth/telemedicine
- Is your mobile app a medical device?
- Reduce cybersecurity vulnerabilities:
  - Adhere to HIPAA security requirements and NIST cybersecurity guidance for critical infrastructure
  - Deploy controls to match actively identified cyber security risks
  - Continuously measure security controls
  - Provide “safe computing” education to employees and users

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