Legal and Regulatory Concerns with Telemedicine

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Agenda:

- 21st Century Cures Act
- Medicare coverage
- Michigan law
- Michigan Medicaid coverage
- Privacy/security
- Fraud and abuse
- Credentialing and privileging
- Licensing
- Medical malpractice

21st Century Cures Act:

- Included a directive from Congress for further study into the use of technology for the delivery of health care services.
- Congress concluded that the ***Centers for Medicare and Medicaid Services (CMS)*** should expand the list of eligible originating sites (i.e., sites where the patient is located) for the delivery of telehealth services.

21st Century Cures Act directs CMS to identify:

- Recipients of Medicare and Medicaid services whose care may be improved by the expansion of telehealth services currently reimbursed by CMS;
- All demonstration projects, models or initiatives being conducted by the Center for Medicare and Medicaid Innovation, which examine the use of telehealth services;
- Types of high-volume services and diagnoses that may be suitable using telehealth platforms; and
- Possible barriers that prevent the expansion of telehealth services currently covered by the Medicare and Medicaid programs.
- CMS to deliver report to Congress by 12/14/2017

21st Century Cures Act directs MedPac to:

- Study telehealth services for which payment is currently made under Medicare Part A &B and private health insurance plans.
- Research approaches that can be taken to expand payments to cover those services that are covered under private health insurance plans but not under Medicare Part A/Part B.
- MedPac will have until 3/15/2018 to deliver a report to Congress.

Medicare Coverage for telehealth

Medicare Part B (Medical Insurance) covers certain services, like office visits and consultations, that are provided:

- Using an interactive 2-way telecommunications system (with real-time audio and video)
- By a doctor or certain other health care provider who isn’t at your location.

If you live in some rural areas:

These services are covered under certain conditions and only if you're located at one of these places:

- Offices of physicians or practitioners
- Hospitals
- Critical Access Hospitals (CAHs)
- Rural Health Clinics
- Federally Qualified Health Centers
- Hospital-based or CAH-based Renal Dialysis Centers
- Skilled Nursing Facilities (SNFs)
- Community Mental Health Centers (CMHCs)

Medicare telehealth-distant site practitioners:

- Physicians
- Nurse Practitioners (NPs)
- Physician Assistants (PAs)
- Nurse-midwives
- Clinical Nurse Specialists (CNSs)
- Certified Registered Nurse Anesthetists (CRNAs)
- Clinical Psychologists (CPs) and Clinical Social Workers (CSWs)
- Registered Dietitians (RDs) or Nutritional Professionals

Medicare telehealth- real-time communication:

- The beneficiary and distant site practitioner communicate via an interactive audio and video telecommunications system that permits real-time communication between them
- Asynchronous “store and forward” technology is covered in Alaska and Hawaii under Federal telemedicine demonstration programs

Medicare telehealth- covered services:

- Telehealth consultations, emergency department or initial inpatient
- Follow-up inpatient telehealth consultations (hospitals and SNFs)
- Office or other outpatient visits
- Subsequent hospital care and nursing facility services
- Individual and group kidney disease education services and diabetes self-management training services
- Behavioral health assessment, intervention and psychotherapy
- End-stage renal disease-related services for home dialysis
- Alcohol and substance abuse assessment and intervention services

Medicare telehealth- covered services

- Telehealth pharmacologic management
- Smoking cessation services
- Individual or group medical nutrition therapy
- Transitional care management services
- Advanced care planning
- Psychoanalysis and family psychotherapy
- Annual wellness visit
- Telehealth consultation

RAND / HEALTH AFFAIRS STUDY

- Study looked at claims data from a cohort of 300,000 employees with access to Teladoc through their employer
- Compared a cohort of telemedicine users to a cohort of non-telemedicine users
- With the telemedicine users, visits to primary care doctors barely decreased, meaning the Teladoc visits were mostly additive(visits that otherwise would not have occurred), rather than substitutive (visits that otherwise would have occurred in person)
- RESULT: Telemedicine cost the payer $45 per patient more than a plan without telemedicine would have.

Direct-To-Consumer Telehealth May Increase Access to Care But Does Not Decrease Spending

OIG to Audit Medicare Telehealth Services

Per July 2016 Medicare Payment Advisory Commission (MEDPAC) Report to Congress:

- Among the 175,000 telehealth claims from distant sites, 95,000 (55%) were without an originating site claim
- Discrepancy could be due to providers not billing the $25 facility fee or because some services inappropriately originated from a patient's home
- Among the distant telehealth claims without an originating site, 53,000 visits (55%) associated with rural beneficiaries and 41,000 (44%) were associated with urban beneficiaries

Michigan telehealth definition:

"**Telehealth**" is defined as the use of electronic information and telecommunication technologies to support or promote long-distance clinical health care, patient and professional health-related education, public health, or health administration, MCL 333.16283(c) (2017)

- Telehealth may include, but is not limited to, telemedicine. A "telehealth service" means a health care service that is provided through telehealth.
- Note, the technology/modality definition of "telehealth" is broader than that of "telemedicine" (the latter requiring real-time, interactive audio or video, or both).

Michigan telemedicine definitions

"**Telemedicine** means the use of electronic media to link patients with health care professionals in different locations. To be considered telemedicine, the health care professional must be able to examine the patient via a real-time, interactive audio or video, or both, telecommunications system, and the patient must be able to interact with the off-site healthcare professional at the time the services are provided."

MCL 500.3476 (2012)

Michigan online prescribing authority:

- Health professional providing telehealth service to a patient may prescribe the patient a drug if both the following are met:
  - The health professional is a prescriber who is acting within the scope of his or her practice; and
  - The drug is not a controlled substance. *Michigan, as of March 2017, joins the minority of states that per se prohibit telemedicine prescribing of controlled substances.*

MCL 333.16285

Michigan online prescribing authority:

A health professional providing telehealth service prescribing a drug must comply with both the following:

- If the health professional considers it medically necessary, he or she shall provide the patient with a referral for other health care services that are geographically accessible to the patient, including, but not limited to, emergency services.
- After providing a telehealth service, the health professional shall make himself or herself available to provide follow-up health care services to the patient or refer the patient to another health professional for follow-up health care services.

MCL 333.16285

Private/commercial payers in Michigan:

Michigan law states that “contracts shall not require face-to-face contact between a health care professional and a patient for services appropriately provided through telemedicine” which includes live video.

MCL 500.3476 (2012)

Michigan Medicaid reimburses for the following services via live video:

- Inpatient consults
- Office or other outpatient consults and services
- Psychiatric diagnostic procedures
- Subsequent hospital care
- Training services, diabetes
- ESRD
- Behavior change intervention, individual
- Behavior health and/or substance abuse disorder treatment
- Education service, telehealth
- Nursing facility subsequent care

Relevant privacy/security threats for a typical telehealth system where provider communicates with patient:

- Breach of confidentiality during collection of sensitive data or during transmission to the provider's system
- Unauthorized access to the functionality of supporting devices as well as to data stored on them
- Untreated distribution of software and hardware to the patient (e.g. certain insulin pumps have been shown to be vulnerable to hacking, instances of unauthorized software, such as file-sharing software installed by health care employees have led to a breach of health information and medical identify theft)

Security controls:

- Data encryption (where data are electronically locked using encryption keys) can ensure that if hacker gains access to raw data, those data will be meaningless.
- Functional types of data encryption: at-rest, in-transit and end-to-end encryption
- At-rest and in-transit encryption rely on encryption methods provided by operating systems and browsers (usually external to telehealth software) and if attacker bypasses access controls, data is meaningless
- End-to-end encryption may be directly incorporated into the telehealth application (information is only ever available at the two endpoints and never in between)

With encryption:

- Anyone with the correct key can retrieve meaningful data
- Access to the underlying information system can be further controlled using authentication and access control mechanisms
- Thus, we can restrict access to information based on the identity of the person accessing the data or his/her role in the organization

HIPAA protections:

- HIPAA privacy and security regulations provide protection for identifiable health information when it is collected and shared by "covered entities," i.e. health care providers who bill electronically using HIPAA standards, health plans and health care clearinghouses

45 CFR sec. 160.102, 164.104

Health Information Technology for Economic and Clinical Health (HITECH):

- Extended HIPAA to “business associates,” i.e. entities that “create, receive, maintain or transmit” identifiable health information to perform a function or service “on behalf of” a covered entity

45 CFR sec. 160.103

Fraud and abuse: Stark / Anti-kickback

- Stark Law provides if a physician / or family member has a financial relationship with the entity the physician may not refer Medicare / Medicaid patients to the entity for designated health services unless an exception exists.
- Anti-kickback prohibits the exchange (or offer to exchange), of anything of value, in an effort to induce (or reward) the referral of federal health care program business.
- Telemedicine providers such as Teledoc advertise the ability for Specialist referral services.

Credentialing and Privileging: CMS Final Rule 42 CFR Part 482 and Part 485, Subpart F:

Telemedicine services must be provided under a written agreement between the hospital or CAH and one or more:

- Distant-site hospitals that participate in Medicare; or
- Distant-site telemedicine entity (such as teleradiology, teleICU, teleneurology) that provides telemedicine services, is not a Medicare participating hospital and provides contracted services in a manner that enables the hospital or CAH using its services to meet all CoPs, particularly those related to credentialing and privileging of providers

Written agreement must:

- Contain provisions requiring the distant-site hospital or telemedicine entity to use a credentialing and privileging process that at least meets the Medicare standards that hospitals are required to use, 42 CFR 482.12(a) and 42 CFR 482.22(a)
- Ensure that the distant-site hospital or telemedicine entity has granted privileges to the individual telemedicine physicians and practitioners providing telemedicine services to hospital/CAH patients, and
- That the distant-site telemedicine physicians or practitioners hold a license issued or recognized by the State where the hospital or CAH is located.

Distant-site telemedicine hospital or telemedicine entity must:

- Provide a list of telemedicine physicians and practitioners who are privileged there and their current privileges at the distant-site hospital or entity to the hospital or CAH
- Distant-site telemedicine entity agreement must state that the entity is a contractor of services to the hospital or CAH which furnishes contracted telemedicine services in a manner that permits the hospital or CAH to comply with all applicable CoPs

Hospital or CAH must:

- Under the terms of the agreement, review the services provided by telemedicine physicians and practitioners covered by the agreement and provide written feedback to the distant hospital or telemedicine entity
- Feedback must address, at minimum, all adverse events or complaints related to telemedicine services provided at the hospital or CAH

Alternative credentialing and privileging for distant site telemedicine entity:

- When telemedicine services are furnished to a hospital's patients through agreement with distant-site telemedicine entity, the hospital's governing body may choose to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site telemedicine entity when recommendations on privileges for those distant-site physicians and practitioners providing services

42 CFR 482.22(a)(4)

Michigan Medicaid licensing requirements:

- Telemedicine services must be provided by a health care professional who is licensed, registered or otherwise authorized to engage in his or her health care profession in the state where the patient is located, MDCH Medicaid Manual, p.490, April 1, 2017
- Behavioral Health Therapy: Must be fully licensed in MI, MDCH Medicaid Manual, p. 461, April 1, 2017

Interstate licensing for physicians:

Interstate medical Licensure Compact: Gives physicians in member states an expedited process for obtaining licenses to practice in multiple states (similar compact for nurses is gaining momentum)

- Alabama, Arizona, Colorado, Idaho, Illinois, Iowa, Kansas, Minnesota, Mississippi, Montana, Nevada, New Hampshire, South Dakota, Utah, West Virginia, Wisconsin, Pennsylvania, and Wyoming—have adopted some version of the Federation of State Medical Board's Interstate Licensure Compact, which permits an expedited process for licensed physicians to apply for other state licenses
- Michigan, Washington, Nebraska, Rhode Island, Washington D.C., Tennessee and Texas and Pennsylvania also have pending legislation to adopt the compact

Common state telemedicine licensure exceptions:

- Physician-to-physician consultations (not between practitioner and patient)
- Educational purposes
- Residential training
- Border states
- U.S. Military
- Public health services
- Medical emergencies (Good Samaritan) or natural disasters
  - Teledoc provided free health visits to Hurricane Harvey victims

Medical malpractice coverage:

- Medical malpractice coverage for physicians rendering telemedicine services in several states can pose significant difficulties
- Scope of medical malpractice coverage is dictated by contract, not statutory law
- While some malpractice insurers provide special riders for telemedicine coverage, many will only cover claims for face-to-face encounters for which the insurer agreed to cover the provider
- Malpractice insurers may not even be licensed in states where patients are receiving telemedicine services from the provider
- Providers must ensure their malpractice insurer is licensed in the same states where patients are served and check the insurance contract to verify the telemedicine claims are covered.

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