TELEHEALTH 2021: THE PANDEMIC AND BEYOND (WE HOPE)

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OVERVIEW

- Data Security and Privacy
- Licensing
- Credentialing
- Reimbursement
- Informed Consent
- Prescribing Controlled Substances

- What’s Next?

CONTEXT

- **January 31, 2020**: the Secretary of the Department of Health and Human Services (HHS) declared a Public Health Emergency (PHE) for COVID-19.
  - This PHE initially lasted 90 days (from January 27).
  - The time period can be, and has been, extended for subsequent 90-day periods unless HHS declares that the PHE no longer exists.
- The PHE has resulted in substantial changes to the provision of telehealth services across the country.
  - Permanent vs. temporary

DATA SECURITY AND PRIVACY

- Health Insurance Portability and Accountability Act (HIPAA)
- Must implement specified physical, technical, and administrative safeguards for e-PHI, including:
  - Transmission security: Implement technical security measures to guard against unauthorize access to e-PHI being transmitted over an electronic communications network
  - Integrity controls (addressable): Implement security measures to ensure electronically transmitted e-PHI is not improperly modified
  - Encryption (addressable): Implement mechanism to encrypt e-PHI information when appropriate

45 CFR 164.312

DATA SECURITY AND PRIVACY

- Must put a system in place that provides secure communication to protect e-PHI.
- Must put a system in place to monitor communications containing e-PHI to prevent security breaches.
- Physical security – even if the communication channel is HIPAA-compliant, providers must ensure that they and their patients are in physically secure locations.
  - If privacy is not possible, HHS recommends "using lowered voices, not using speakerphone, or recommending that the patient move to a reasonable distance from others when discussing PHI."

DATA SECURITY AND PRIVACY

- HIPAA: Business associates agreements
- Other treatment providers are not business associates providing treatment (45 CFR 160.103)
- May need business associate agreements with vendors or other outsiders who assist with telemedicine, including
  - Entity that transmits PHI and has regular access to PHI
    - Not "conduits"
  - Entity that stores PHI

DATA SECURITY AND PRIVACY

- HIPAA: Business associates agreements
- Exceptions:
  - Members of workforce
    - You have control over person while onsite
  - Members of organized health care arrangement (OHCA)
    - Integrated delivery of patient care

DATA SECURITY AND PRIVACY: CHANGES IN THE PANDEMIC

- HHS Office of Civil Rights (OCR) issued a “Notification of Enforcement Discretion” permitting covered health care providers to use popular communications applications without risking penalties for violations of HIPAA rules for the “good faith” provision of telehealth services.
  - May use “non-public facing” video chat applications like Apple FaceTime, Facebook Messenger video chat, Google Hangouts video, Zoom, and Skype, etc.
  - May use “non-public facing” text-based applications like Signal, Jabber, Facebook Messenger, Google Hangouts, WhatsApp, and iMessage
  - May not to use “public-facing” applications such as Facebook Live, Twitch, etc.

DATA SECURITY AND PRIVACY: CHANGES IN THE PANDEMIC

- OCR will exercise “enforcement discretion” regarding providers who deliver services without meeting all HIPAA requirements.
  - OCR Will not penalize providers for “good faith” use of telehealth services.
  - What about known security risks?
- Bad actors.
  - Increased efforts to access sensitive information that is now more vulnerable.

DATA SECURITY AND PRIVACY: CHANGES IN THE PANDEMIC

- For more security, use technology vendors that are HIPAA compliant and will enter into HIPAA business associate agreements.
  - Vendors advising OCR that they provide HIPAA-compliant video communication products and will enter into HIPAA business associate agreements:
    - 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, and Spruce Health Care Messenger
  - OCR has not reviewed these vendors' business associate agreements.
- Other technology vendors may also offer HIPAA-compliant video communication products.

DATA SECURITY AND PRIVACY: WHAT'S NEXT?

- Many calls to return to pre-pandemic requirements to protect patient privacy
- Office of the National Coordinator of Health Information Technology published final rules adding safeguards for e-PHI
  - Not directly tied to telehealth services, but will likely impact

DATA SECURITY AND PRIVACY: WHAT'S NEXT?

- Enhanced training for providers regarding patient privacy.
- Ensure that appropriate business associate agreements are in place.
- Greater regulatory guidance and enforcement regarding cybersecurity.
- Push for greater access to adequate broadband connectivity.

LICENSING

- Covers a host of practitioners: DOs, licensed behavioral analysts, marriage and family therapists, MDs, NPs, PAs, professional counselors, psychologists, RNs, SWs, etc.
- General rule: Practitioner must be licensed in the state where the **patient** is located and comply with that state's licensing and scope of practice laws.

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LICENSING: A VARIETY OF STREAMLINED PROCESSES

- Interstate licensure compacts.
  - Interstate Medical Licensure Compact; Nurse Licensure Compact; Psychology Interjurisdictional Compact.
- Licensure by endorsement/reciprocity.
  - *E.g.*, Virginia: physicians, psychologists, nurses, social workers.
- Contiguous states.
  - *E.g.*, Ohio: physicians "residing on the border of a contiguous state."
- Telehealth registration.
  - *E.g.*, Florida: out-of-state telehealth registration.

LICENSING: SCOPE OF PRACTICE AND OTHER RULES

- Supervision requirements, prescribing limitations, etc.
- Check first! Some states have telemedicine-specific rules
  - *E.g.*, Maryland imposes a variety of requirements and safeguards.

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LICENSING: CHANGES IN THE PANDEMIC

- Most states have, at least temporarily, relaxed licensure requirements.
  - *E.g.*, Florida: eligible healthcare professionals licensed in another state may provide telehealth services to patients in Florida without licensure or registration.
- The Federation of State Medical Boards has a helpful list of states that have modified in-state licensure requirements for telehealth in response to the COVID-19 PHE:
  - https://www.fsmb.org/siteassets/advocacy/pdf/states-waiving-licensure-requirements-for-telehealth-in-response-to-covid-19.pdf

LICENSING: WHAT'S NEXT?

- It's a mixed bag.
  - Some licensure changes appear permanent.
  - Emergency orders tied to the PHE that relax licensure requirements will be lifted but may be followed by some degree of increased licensure portability.

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CREDENTIALING

- Licensing vs. credentialing
  - Licensing: Obtaining authorization practice medicine
    - State by state process
  - Credentialing: Verification of practitioners' education, insurance, licensing, etc. to ensure they meet the standards of practice
    - Hospital or healthcare facility process
- Each site delivering telehealth services must credential the provider

CREDENTIALING

- Purpose: Protect patients by ensuring that telehealth providers meet standards set out in state regulations and hospital policies.
- Problem: Time-consuming administrative process, especially for rural facilities.
  - Over $7,000 a year on credentialing application for one state.
  - Administrators spend 20 hours to credential every provider.
  - Two to three months before a provider starts.

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CREDENTIALING

- Choice for many rural hospitals:
  - Contract with distant providers for telehealth services
  - Require patients to travel to receive that particular care or simply go without
- Solution: The option of credentialing by proxy
  - Allows the hospital receiving telehealth services to accept the credentialing decisions of the distant site hospital where the provider is located

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CREDENTIALING

- Be careful:
  - Hospital bylaws must permit credentialing by proxy
  - To participate in and receive reimbursement from Medicare or Medicaid programs, a hospital must be certified as complying with the Medicare Conditions of Participation (CoPs).

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CREDENTIALING

- CoPs requirements:
  - Written agreement
  - Distant site participates in Medicare
  - Telehealth provider is privileged at distant site
  - Current list of provider’s privileges is given to originating site
  - Provider is licensed/license recognized by state of originating site
  - Originating site reviews provider’s performance and provides this information to distant site
  - Originating site must inform distant site of any adverse events/complaints regarding the provider’s services
- Requirements differ slightly from facility to facility

CREDENTIALING: PANDEMIC

- The Federation of State Medical Boards have assisted states to expedite credentialing.
- The CARES Act:
  - As part of the Coronavirus Aid, Relief, and Economic Security ("CARES") Act, Congress appropriated $200 million in funding for the COVID-19 Telehealth Program (the "Program").
  - Available to nonprofit and public eligible health care providers.
  - The Program has funded several million dollars in requests for credentialing assistance.

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CREDENTIALING: WHAT'S NEXT?

- As with licensing, there are industry calls to streamline the credentialing process.
  - Will states cooperate?
  - Providers will benefit from the use of technology offered by private entities.
- Proposal: Expanding the scope and funding of the CARES Act Program, including for use in credentialing.
- The biggest impediment to streamlining of the credentialing process: States.

REIMBURSEMENT

- Medicare
- Medicaid
- Commercial

REIMBURSEMENT: MEDICARE

- Medicare reimburses for only limited telehealth services.
- Limited originating site (patient's location):
  - In a rural Health Professional Shortage Area (HPSA) or in a county outside of a Metropolitan Statistical Area (MSA) and
  - In a facility allowed by Medicare, *e.g.*, physician/practitioner office, hospital, SNF, etc., but generally not the patient's home.

REIMBURSEMENT: MEDICARE

- Providers: (i) physicians, (ii) NPs, (iii) PAs, (iv) nurse-midwives, (v) CNSs, (vi) certified registered nurse anesthetists, (vii) CPs and CSWs, and (viii) registered dietitians or nutritional professionals.
- Technology: interactive audio and video telecommunications systems that permits real-time communication.
  - Not to be confused with non-telehealth services like CCM/TCM services, virtual check-ins, or e-visits.

REIMBURSEMENT: MEDICARE CHANGES IN THE PANDEMIC

- CMS has taken numerous steps to expand Medicare telehealth coverage during the PHE.
  - Those actions during the PHE "have unleashed an explosion in telehealth innovation, and we're now moving to make many of these changes permanent." HHS Secretary Alex Azar.
- CMS is limited in its ability to expand Medicare telehealth coverage.
  - Must fit within statutory framework.
  - The PHE offers more leeway but is temporary.
- Many permanent changes will need to wait for Congressional action.

REIMBURSEMENT: MEDICARE CHANGES IN THE PANDEMIC

- Expansion of permissible originating sites, allowing telehealth services to be provided regardless of where the beneficiaries are located, including in their residences and outside designated rural areas.
- Expansion of services.
- Reimbursement at in-person rates.
- Reduced or waived cost-sharing.
- Practicing across state lines.
  - **Caution**: This is also subject to requirements set by the states involved.

REIMBURSEMENT: MEDICARE CHANGES IN THE PANDEMIC

- Relationship: Physicians may see both new and established patients for telehealth and other visits using communications technology.
- Nursing facilities: In response to industry concerns about the 30-day frequency limitation on subsequent telehealth nursing facility visits, CMS reduced the frequency limitation to 14 days.
  - Intent: Promote telehealth in nursing facility settings while ensuring that providers are not disincentivized to provide in-person care.
- Scope of Practitioners.

REIMBURSEMENT: MEDICARE CHANGES IN THE PANDEMIC

- Direct supervision: Physicians may supervise services through interactive audio-video communication.
- Supervision of residents.
- Modality: For telehealth services, a “telecommunications system” would mean “multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.”
  - Audio-only is also allowed in some circumstances.

REIMBURSEMENT: MEDICARE CHANGES IN THE PANDEMIC

- Expanded services: CMS has significantly expanded the list of services that can be provided by telehealth:
  - https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes
  - The expanded services list includes codes added for the duration of the PHE.
  - More recently, some codes initially added only for the duration of the PHE are now permanent.
- Federally Qualified Health Centers and Rural Health Clinics can provide telehealth services to patients wherever located.
  - This includes coverage of certain audio-only telephone evaluation and management services.

REIMBURSEMENT: WHAT'S NEXT FOR MEDICARE?

- "I can't imagine going back." CMS Administrator Seema Verma.
- There are about a dozen bills before Congress right now, *e.g.*, the "Permanency for Audio-Only Telehealth Act":
  - Remove technological and geographic restrictions that inhibit telemedicine services in rural areas lacking adequate broadband connectivity to support audio-visual telemedicine technology.
  - Cover and reimburse providers for evaluation and management services and mental and behavioral health services even if using an audio-only telehealth platform.
  - Allow HHS to add medical services for audio-only telehealth coverage.
  - The Act would also allow Medicare beneficiaries to receive Medicare-covered telehealth services from their home.

REIMBURSEMENT: MEDICAID

- Rates and conditions vary from state to state
  - Conditions: may include requirements as to the electronic mode of communication (*e.g.*, synchronous audio and video) and/or documentation requirements.
  - Parity: some states have telehealth parity with respect to the types of services and rates of services.

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REIMBURSEMENT: MEDICAID CHANGES IN THE PANDEMIC

- Relaxation of conditions for payment:
  - Types of practitioners
  - Types of services
  - Required electronic modes of communication
  - Establishment of physician-patient relationship

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REIMBURSEMENT: MEDICAID CHANGES IN THE PANDEMIC

- For example, Michigan, like many other states, expanded telemedicine services authorized for Medicaid as follows:

The purpose of this guidance is to allow flexibility related to telemedicine audio/visual requirements to protect the health and welfare of beneficiaries and providers while maintaining access to vital services during the COVID-19 pandemic. This guidance will be in effect for 30 days following the termination of the Governor's Declaration of a State of Emergency Order (2020-04, COVID-19), or on the first of the following month, whichever is later.

General Telemedicine Policy Expansion

Current telemedicine policy requires both audio and visual service delivery, and when all possibilities to provide services using both audio and visual have been deemed not possible, due to the COVID-19 pandemic the Michigan Department of Health and Human Services (MDHHS) is expanding telemedicine policy.

During the period with dates of service referenced above, all codes on the telemedicine database (which encompass primary care, behavioral health, etc.) will be allowed for the service delivery method **telephonic (audio) only**. (See telemedicine database attached.)

REIMBURSEMENT: COMMERCIAL

- Parity: some states require private insurers to reimburse for telehealth services, *e.g.*, Virginia:

C. An insurer, corporation, or health maintenance organization shall not exclude a service for coverage solely because the service is provided through telemedicine services and is not provided through face-to-face consultation or contact between a health care provider and a patient for services appropriately provided through telemedicine services.

D. An insurer, corporation, or health maintenance organization shall not be required to reimburse the treating provider or the consulting provider for technical fees or costs for the provision of telemedicine services; however, such insurer, corporation, or health maintenance organization shall reimburse the treating provider or the consulting provider for the diagnosis, consultation, or treatment of the insured delivered through telemedicine services on the same basis that the insurer, corporation, or health maintenance organization is responsible for coverage for the provision of the same service through face-to-face consultation or contact.

REIMBURSEMENT: WHAT'S NEXT FOR MEDICAID AND COMMERCIAL PAYORS?

INFORMED CONSENT

- Standard (generally): understand the nature of the care, along with the anticipated benefits, risks, and alternatives
- Spoken or written consent?

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INFORMED CONSENT: CONSENT FORMS

- Advisable for form to be specific to telehealth, or specifically contemplate telehealth
- Select considerations:
  - Security
  - Technical issues/decision-making
  - Appropriateness of telehealth
  - Have other intake forms already been executed, *e.g.*, Notice of Privacy Practices, Financial Responsibility, etc.?

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PRESCRIBING

- Telehealth providers are generally subject to prescribing rules set under licensure regulations
- Additional federal and state limitations for telehealth
  - Controlled substances
  - Patient location
  - Physician-patient relationship
  - Emergency
  - Medication-assisted treatment of an opioid use disorder

PRESCRIBING: CHANGES IN THE PANDEMIC

- The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (the "Haight Act")
  - The Haight Act prohibits prescribers from issuing a valid prescription for a controlled substance via internet, including using telehealth services, without first conducting at least one in-person medical evaluation
  - A PHE is an exception to the in-person medical examination requirement
- When HHS declared a PHE, it triggered this exception to the "in-person medical evaluation" requirement for online prescribing

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PRESCRIBING: CHANGES IN THE PANDEMIC

- DEA now allows registered practitioners to issue prescriptions for all schedule II-V controlled substances to patients with no in-person medical evaluation if:
  - The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice,
  - The telemedicine communication is conducted using an audio-visual, real-time, two-way interactive communication system, and
  - The practitioner is acting in accordance with applicable federal and state laws.
- Qualifying practitioners can prescribe buprenorphine to new and existing patients with opioid use disorder based on a telephone evaluation.

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PRESCRIBING: CHANGES IN THE PANDEMIC

- For more on the specific requirements for practitioners, see:
  - DEA's How to Prescribe Controlled Substance to Patient During the COVID-19 Public Health Emergency (https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-023)(DEA075)Decision_Tree_(Final)_33120_2007.pdf)
  - DEA's COVID-19 Information Page (https://www.deadiversion.usdoj.gov/coronavirus.html)
  - DEA's Letter to physicians about buprenorphine (https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20(Final)%20+Esign.pdf)

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PRESCRIBING: CHANGES IN THE PANDEMIC

- In conjunction with HHS' action, numerous states indicated that they would not impose penalties for noncompliance with state regulatory requirements that an in-person medical examination precede issuing a prescription for a controlled substance
  - Be careful: While many restrictions have been loosened, they vary from state to state

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PRESCRIBING: POST-PANDEMIC

- Some discussion of incremental changes to assist in addressing the opioid epidemic, although this is not really tied to the pandemic.
- More likely that, given the risks of loosening telemedicine prescribing restrictions in the opioid epidemic, in-person prescribing requirements will likely return

DON'T FORGET!

- *Federal v. State*: the adjustments we've discussed are largely federal. Check your state!
  - If your services cross state lines, check both states!
- *Licensure*: what adjustments has your state made for licensure?
- *Consent*: be sure you know what you need for informed consent, especially if telehealth services cross state lines

DON'T FORGET!

- *Standard of care*: this is an open question, but generally there is no different standard for change from telehealth and in-person care
- *Insurance*: check your insurance before providing expanded telehealth services, *e.g.*, across state lines.

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RESOURCES

- Keep an eye on guidance from HHS at telehealth.hhs.gov
- Center for Connected Health Policy: https://www.cchpca.org/resources/covid-19-telehealth-coverage-policies

QUESTIONS?
NEED MORE INFORMATION?

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