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# Legal Issues in Implementing Telehealth Programs During the Pandemic and Beyond

Presented by:

- Andrea Frey, Esq.
- Jeremy Sherer, Esq.

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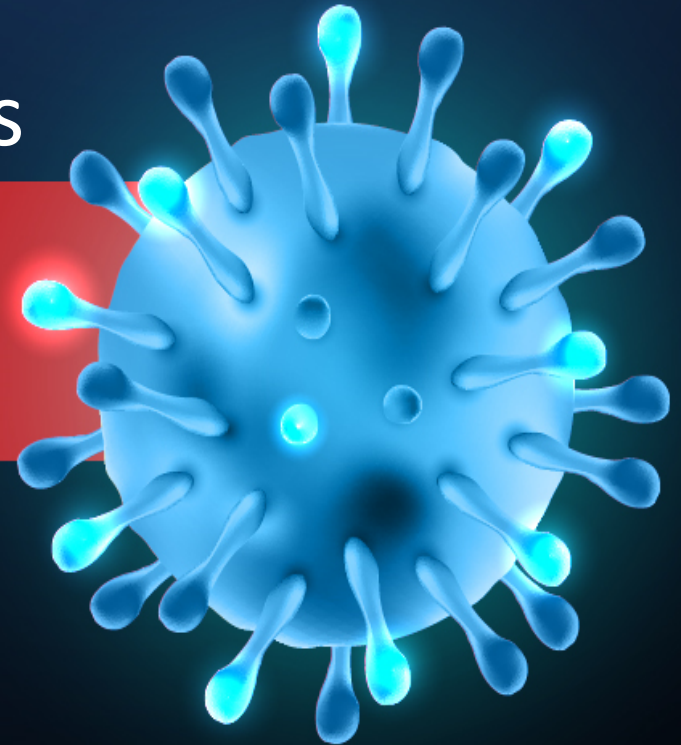
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## Coronavirus COVID-19

Updates and Resources

For links to guidance from various  
state and federal agencies regarding  
COVID-19 go to

<http://www.hlbccovid19.com>



# Agenda

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## 1. Overview of Telehealth Regulatory Landscape During the PHE and Beyond

### ○ Coverage and Reimbursement

- Medicare
  - Overview of Coronavirus Aid, Relief, and Economic Security (CARES) Act and Section 1135 Waivers
  - “Medicare Telehealth Services”
  - Long-Term Care Implications
  - Billing Issues
- Medicaid
- Commercial

### ○ Prescribing via telehealth

### ○ Fraud and Abuse

### ○ Privacy

### ○ Licensure

### ○ Medical Staff

### ○ Patient Consent

### ○ Malpractice

## 2. Making Telehealth Sustainable Post-Pandemic: Telehealth Compliance Tools

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# Coverage and Reimbursement

# Overview of Government Action

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## Section 1135 Waivers

- Section 1135 of the Social Security Act (“Section 1135”) authorizes the Secretary of the US Department of Health and Human Services (“HHS”) to temporarily modify or waive certain Medicare, Medicaid, Children’s Health Insurance Program (“CHIP”), and Health Insurance Portability and Accountability Act (“HIPAA”) requirements in a declared national emergency or disaster.
  - Following President’s proclamation on March 13, HHS Secretary Alex Azar invoked authority and announced a number of nationwide blanket waivers, including a waiver related to telehealth.
  - Secretary’s authority under Section 1135 also allows CMS to grant waivers to states that request CMS to temporarily waive compliance with certain requirements for Medicaid programs during public health emergency.

## CARES Act

- On March 27, Congress the CARES Act., which contains many measures to increase the use of telehealth through the waiver of certain in-person requirements and increased funding to enhance access to telehealth services.

## CMS Interim Final Rule

- On March 30, CMS issued an interim final rule introducing additional temporary regulatory waivers and new rules to provide further flexibility in responding to COVID-19.

# Medicare Telehealth Services (Pre-COVID-19)

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## **Historically, “Medicare telehealth services” are only covered when:**

1. The patient is located at an eligible “originating site” facility;
2. The patient is located in a rural health professional shortage area (“HPSA”) (unless an exception applies);
3. The service rendered is on the list of “Medicare telehealth services”;
4. The service is rendered by an approved type of provider; and
5. The service is furnished via synchronous audio-video communication.

# Medicare Telehealth Services during PHE

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## **Originating Site Requirement**

During the COVID-19 PHE, “Medicare telehealth services” can be provided to patients wherever they are located, even in the home.

Patients do not need to be located in rural areas.

## **Covering More Than “Medicare Telehealth Services”**

In addition to the “Medicare telehealth services” normally covered, CMS is covering 80 new services during the COVID-19 PHE.

## **Service must be rendered via synchronous audio-video technology**

Waived – consults by telephone are acceptable where audio-video communication isn’t possible.

# Medicare Telehealth Services during PHE

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## **Service must be provided by an approved category of provider**

Largely in place, but the requirement that the provider be licensed in the state where the patient is located is waiving for purposes of Medicare and Medicaid reimbursement. Don't forget about state law requirements.

FQHCs and RHCs added as eligible distant site providers. PTs, OTs, SLPs added as approved providers.



# Other Waivers of Medicare Limitations on Telehealth

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## **Hospital, Critical Care, and SNF Telehealth Frequency Limits**

Prior to the PHE, hospitals were limited to providing (and billing for) subsequent hospital care once per three-day period, critical care consults could only be billed once per day, and subsequent skilled nursing facility (SNF) services could only be billed once per 30-day period. During the PHE these telehealth frequency limitations all have been waived.

## **Home Dialysis**

In-person requirements related to End Stage Renal Disease (ESRD) clinical assessments waived.

## **Hospice/Home Health**

Requirement that Medicare beneficiaries be certified to receive Medicare covered hospice benefits via an in-person face-to-face encounter waived during PHE, meaning hospice physician or nurse practitioner may conduct such encounters via telehealth.

Home Health Agencies and hospices may also provide services via may utilize remote patient monitoring, telehealth or other telecommunications technologies in the course of providing services if it is provided for in the patient's plan of care or is feasible and appropriate to do so for purposes related to palliative and management of the beneficiary's terminal illness, respectively.

# Medicare Billing for Telehealth Services

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“Medicare Telehealth Services” should be billed with the 95 modifier, and **place of service (POS) 02**, indicating that the service was provided via telehealth.

For non- “Medicare telehealth services,” bill with the POS which *would have applied*, and the 95 modifier.

# Medicare Billing for Telehealth Services

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## Originating Site Facility Fee and Professional Fees

- The Originating Site Fee, Q3014, can only be billed when the patient receives treatment at the originating site. So, when the patient is located at home, the originating site fee cannot be billed.
- Re-located PBDs *can* bill the originating site fee, because the patient is “at” the originating site.
- Professional fees paid to clinicians can vary based upon where they are at the time the services at issue are rendered. However, for the duration of the PHE, clinicians can bill using the place of service (“POS”) code that *would have* applied, but for the PHE.

# Medicare Reimbursement Post-PHE

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- CMS will “tinker around the edges,” but “Medicare telehealth services” requirements are in the Social Security Act, and can only be modified through an act of Congress.
- Most discussion around rural/urban originating site issue.

# State Medicaid Programs

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State Medicaid programs generally have discretion to determine how telehealth covered and reimbursed, and so vary widely by state.

CMS has encouraged state Medicaid programs to take advantage of waivers and Medicaid expansion strategies in order to deal with the pandemic by increasing coverage and reimbursement of telehealth services.

Many state Medicaid programs have done so in response, such as in Missouri, Delaware, and Washington, D.C.

# Commercial Payors

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There is tremendous variation among the states regarding telehealth parity by commercial payors, both concerning coverage and reimbursement.

## Payment Parity Legislation

- Many state agencies have taken action for the duration of the COVID-19 PHE requiring commercial insurers to pay the same amount for services provided via telehealth as they would if the services were provided in person.
  - For example, California's DMHC has issued an All Plan Letter (APL) calling for plans to cover telehealth services, and pay for them at the same level as they would if the services were provided in-person.
  - Massachusetts Governor Charlie Baker's March 15 Order Expanding Access to Telehealth Services and to Protect Health Care Providers.

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# Prescribing via Telehealth

# Controlled Substances Act (as amended by the Ryan Haight Act)

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## **Prescribing controlled substances requires a valid prescription.**

A “valid prescription” is one that is issued “for a legitimate medical purpose in the usual course of professional practice” by either:

1. A practitioner who has conducted at least 1 in-person medical evaluation of the patient, or
2. A covering practitioner.

→ What is an “in-person medical evaluation”?

→ What is a “covering practitioner”?



# In-Person Medical Evaluations and Covering Practitioners

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**In Person Medical Evaluation:** “A medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.”

**Covering Practitioner:** “With respect to a patient, a practitioner who conducts a medical evaluation (other than an in-person medical evaluation) at the request of a practitioner who:

- (i) has conducted at least 1 in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine in the past 24 months,” **and**
- (ii) “is temporarily unavailable to conduct the evaluation of the patient.”

## Public Health Emergency Exception

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**There is an exception to the Ryan Haight Act for live, audio-video examinations performed “during a public health emergency declared by the Secretary ...”**

Secretary of Health and Human Services Alex Azar declared a public health emergency concerning COVID-19 on January 31, 2020.

The Drug Enforcement Administration (“DEA”) and state governments then issued guidance setting forth how controlled substances can be prescribed during the PHE.

## DEA Guidance on Controlled Substances

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**DEA-registered practitioners may prescribe controlled substances to “established” and “new” patients without an in-person examination during the PHE.**

**Established patients:** synchronous, audio-video interaction *or* synchronous audio interaction (*i.e.*, telephone call) is sufficient.

**New patients:** synchronous audio-video interaction is required.

**Covering practitioners:** synchronous, audio-video interaction *or* synchronous audio interaction (*i.e.*, telephone call) is sufficient.

# DEA Guidance on Buprenorphine

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**“DATA-waived” practitioners may prescribe buprenorphine to new or established opioid use disorder patients without an in-person examination during the PHE.**

**Established patients:** synchronous, audio-video interaction *or* synchronous audio interaction (*i.e.*, telephone call) is sufficient.

**New patients:** synchronous, audio-video interaction *or* synchronous audio interaction (*i.e.*, telephone call) is sufficient.

- Evaluating practitioner must still determine that an adequate patient evaluation can be conducted over the telephone.
- The prescription also must otherwise be consistent with the practitioner’s obligation under the Controlled Substances Act, DEA regulations and general standards of practice to only prescribe controlled substances for a legitimate medical purpose while acting in the usual course of his or her professional practice.

# Prescribing via Telehealth Post-PHE

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- DEA appears to be working on the “telemedicine exception,” which would allow providers to obtain a special registration to enable them to prescribe controlled substances without a prior in-person examination.
  - Timeline is unknown post-pandemic.

## State Law and Controlled Substances

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### **Controlled substances prescribing practices must also comply with state law.**

- Has the state where the patient is located issued guidance consistent with the DEA for purposes of controlled substances?
- Has the state where the patient is located issued guidance consistent with the DEA for purposes of buprenorphine?
- Does the state Medicaid program have applicable coverage requirements or any additional requirements beyond the federal “floor” (e.g., Connecticut, MassHealth)?

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# Fraud and Abuse

# Fraud and Abuse during the PHE

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Ordinarily, routine reductions or waivers of costs owed by federal health care program beneficiaries, including coinsurance and deductibles, potentially implicate the antikickback statute, the civil monetary penalty and exclusion laws related to kickbacks, and the civil monetary penalty law prohibition on inducements to beneficiaries.

**The Office of Inspector General (OIG) is exercising enforcement discretion and will not subject physicians and other practitioners to OIG administrative sanctions for reducing or waiving cost-sharing obligations for telehealth services as long as both of the following conditions are satisfied:**

- The services provided are consistent with applicable coverage and payment rules, and
- Furnished during declaration of public health emergency

Additional considerations:

- Providers are not required to waive coinsurance/deductibles
- Free telehealth services will not be considered an inducement



# Fraud and Abuse Post-PHE

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CMS telehealth visits increased from 13,000 per week pre-pandemic to 1.7 million during the pandemic. **Increased utilization creates increased scrutiny.**

*“We are monitoring program integrity implications such as practitioners who may be offering shorter telehealth visits with patients to maximize payment, or billing more visits than are possible in a day. We know the path forward to expanding telehealth relies on CMS addressing the potential for fraud and abuse in telehealth, as we do with all services.”*

*- Administrator Verma*

Additionally, Medicare telehealth services highlighted in the OIG Work Plan, meaning scrutiny and enforcement actions more likely.

# Fraud and Abuse Post-PHE

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## New focus on telehealth, or continuation of pre-pandemic trends?

- **“Operation Brace Yourself.”** 2019 nationwide takedown led by Department of Justice, \$1 billion in fraudulent telehealth claims.
- **July 2020 Offshoot:** *“largest fraud operation in the history of the Southern District of Georgia.”* 26 charged in \$480 million fraud, including physicians, NPs, owners of telehealth companies, brokers of patient data, and DME company owners.
- Pre-pandemic, HHS-OIG indicated future emphasis on behavioral health utilization via telehealth among Medicaid beneficiaries.

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# Health Privacy

# Health Privacy

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**During the PHE, HHS OCR is exercising enforcement discretion and waiving penalties for HIPAA violations against providers that “serve patients in good faith through everyday communication technologies,” including FaceTime, Google Hangout, Facebook Messenger and Skype.**

- Applies to ALL services and medical conditions treated via telehealth, not just COVID-19 related services
  - Facebook Live, Twitch, TikTok and similar video communications should not be used
  - Providers are encouraged to notify patients that these third-party applications potentially introduce privacy risks
- *Reminder – 42 CFR Part 2 (federal regulations governing confidentiality of substance use disorder records) & state privacy laws still applicable.*
- *In California, Governor Newsom issued an [order](#) on April 3<sup>rd</sup> that relaxes certain state privacy and security laws for medical providers, including H&S Code § 1280.15 and Civil Code § 1798.82, so they can provide telehealth services with significantly less risk of being penalized.*

# Health Privacy Post-PHE

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**Waivers to HIPAA and state-level privacy laws most likely temporary, so it is important to ensure that going forward, providers have reasonable and appropriate security safeguards in place to ensure that telehealth services may be provided confidentially and securely.**

→ Reminder that telehealth provision or use does **not** alter a covered entity's obligations under HIPAA, nor does HIPAA contain any special section devoted to telehealth. Therefore, if a covered entity utilizes telehealth that involves PHI, the entity must meet the same HIPAA requirements that it would for a service provided in person.

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# Additional Practitioner Considerations

# Practitioner Licensure

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When treating a patient via telehealth, the provider must generally be licensed in the state where the patient is located. CMS has waived for purposes of Medicare and Medicaid reimbursement, however *state law still applies*.

## **Some states have waived licensure requirements in response to COVID-19.**

- In California, health care practitioners licensed in other states but not in California can treat California patients, as long as the facility with which they are working has received approval from California's Emergency Medical Services Authority.
  - In Massachusetts, Gov. Baker issued an order calling for out-of-state physicians to be granted emergency licenses to treat Massachusetts patients.
- *The Federation of State Medical Board is tracking state waivers to licensure requirements [here](#).*

# Licensure Post-PHE

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State licensure requirements won't go away post-pandemic. Always ensure that telehealth practices comply with the rules of the appropriate licensing board(s) for the practitioners delivering telehealth services (including, but not limited to, any rules specific to telehealth), including applicable scope of practice rules.

## **What about the Interstate Medical Licensure Compact?**

- About 60% of states are part of the IMLC.
  - But California, Florida, Texas and Massachusetts are among the states that have NOT joined the IMLC (each state needs to join individually.)



# Provider Credentialing

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Before a practitioner may provide services in a hospital setting, he or she must have their qualifications evaluated and verified. Once a practitioner is credentialed, the hospital engages in the privileging process, which will assess the practitioner's competence in a specific area of care.

**Practitioners who are currently credentialed and privileged by the organization, who would now provide the same services via a telehealth link to patients, do not require any additional credentialing or privileging.**

For practitioners not currently credentialed or privileged, could require granting temporary or disaster privileges – be sure to check your Medical Staff Bylaws and applicable accreditation standards. (See the Joint Commission's website, which [includes sample language](#) covering what is required to grant privileges to volunteer licensing independent practitioners in an emergency or disaster situation.)

# Patient Consent

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Many states (as well as state Medicaid programs) require clinicians to obtain a patient's consent, either verbal or written, before rendering services via telehealth. However, even among states which do require such consent, details vary considerably. Consent should also be documented in patient's medical record.

- Some states have waived requirement during emergency.
- Regardless of waivers, this is a clinical best practice that should be implemented and documented in some capacity, both by distant and originating site providers.

# Malpractice Insurance

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Some malpractice insurance policies are drafted to limit coverage to services provided in-person, or to services provided to patients located in a particular state.

→ Important to verify that a clinician's malpractice insurance covers services provided via telehealth, including to patients physically located in another state.

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# Implementing a Sustainable Telehealth Program

# Building a Telehealth Compliance Plan

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**While telehealth is just another way to deliver health care services, not its own discipline, it impacts operations enough that providers should implement a telehealth-specific compliance plan that addresses the considerations discussed above.**

# Building a Telehealth Compliance Plan

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- Policies and Procedures specific to telehealth
- Checklists, Charts, Workflows
  - Telehealth billing protocols by payer (e.g., Medicare, commercial, Medicaid).
  - Practitioner issues (such as scope of practice requirements and when telehealth clinically appropriate)
  - Documentation and patient consent requirements.
- Prepare agreement templates specific to telehealth (e.g. amend professional services agreements to incorporate provision of telehealth) and ensure review process in place for vendor agreements
- Workforce training on telehealth work flow and operations

# Questions?

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**Andrea Frey**

**Digital Health Co-Chair**

**[afrey@health-law.com](mailto:afrey@health-law.com)**

**415-875-8507**

**San Francisco**



**Jeremy Sherer**

**Digital Health Co-Chair**

**[jsherer@health-law.com](mailto:jsherer@health-law.com)**

**617-532-2705**

**Boston**