CALIFORNIA TELEHEALTH RESOURCE CENTER

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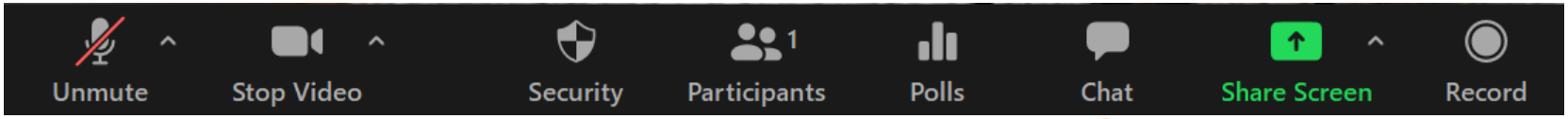
Telemedicine **Policy Update**

The past, present, and future of the regulations of telemedicine.

Zoom Tips



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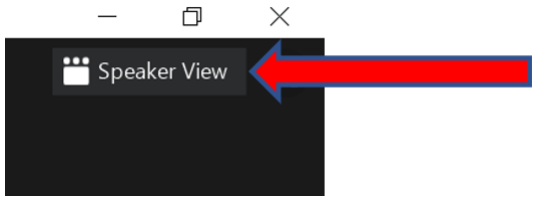

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Meet Your Presenter

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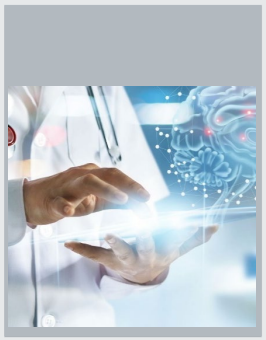
Telemedicine Policy Update

past, present and future of the regulation of telemedicine



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FOLEY & LARDNER LLP

March, 2023

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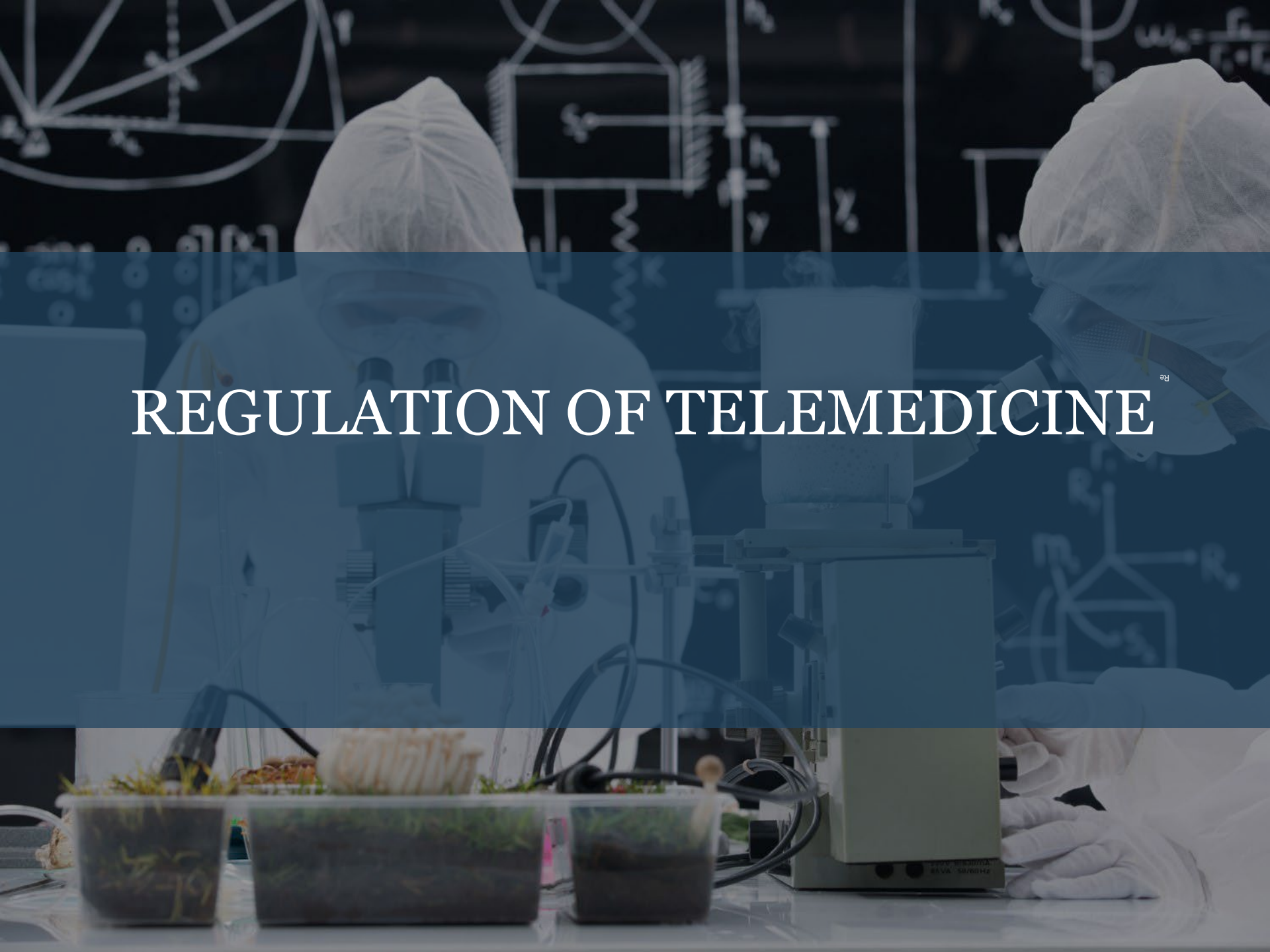
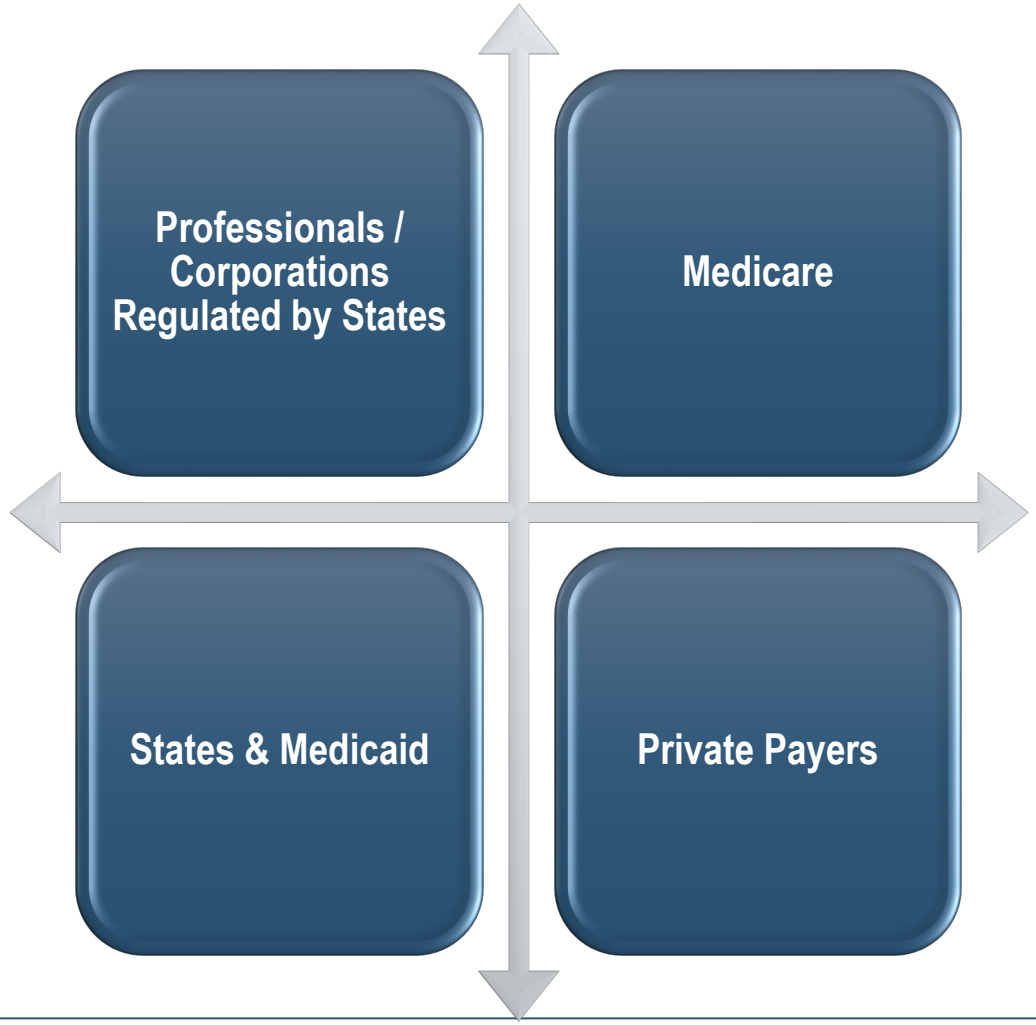
Agenda

- **Telemedicine Pre and Post COVID-19**
  - National Trends: Licensure and Practice Standards
  - Medicare/Reimbursement
  - HIPAA
  - DEA/Prescribing
- **OIG Fraud & Abuse Focus**
- **Virtual Clinical Trials**



REGULATION OF TELEMEDICINE

Overlapping Layers of Regulation



Overlapping Layers of Telemedicine Policy

- Professionals and corporations are regulated at the state level
  - Physicians, Physicians Assistants, Nurse Practitioners, Nurses, Counselors, etc.
  - Tele-services companies, medical groups, insurance companies, etc.
- Medicare
  - Federal “definitions” of telemedicine, and some significant restrictions
  - No regulations *per se*; only conditions of payment (and concepts, definitions)
- States & Medicaid
  - Medicaid varies by state; managed plans (MCOs) are regulated at state level
  - States can dabble in other areas of regulation: licensing boards, insurance, coverages
- Private Payors
  - Coverages can vary by company and plan
  - Compliant with state law (we hope), but limited transparency otherwise

Regulatory Considerations

- Licensure (State controlled)
- Practice Standards (State controlled)
- Prescribing (Federal and State)

Federal regulation via Medicare/Medicaid Reimbursement requirements

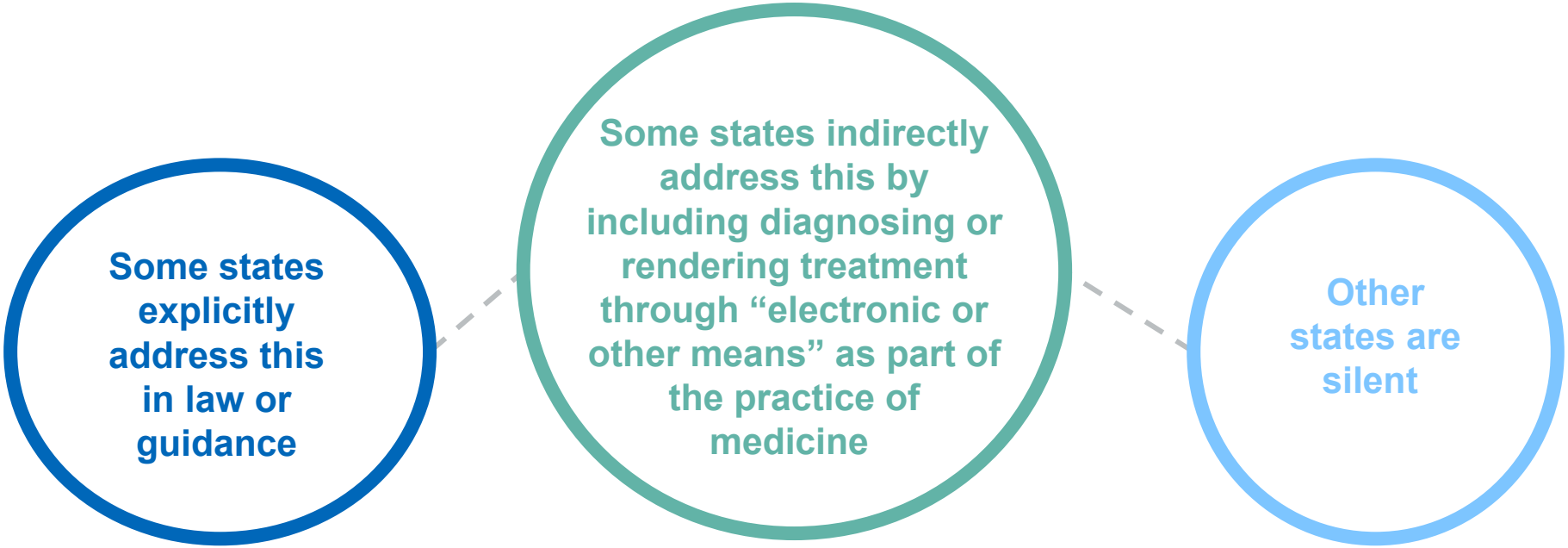
National Trends:

State Licensure & Practice Standards

Licensing

- Regarding medical practice rules, it is generally accepted that the law that governs the consult is the state where the patient is located at the time of the consult. This is the locus of care.

- State law expressly or implicitly requires licensure if the patient is located in the state at the time of the consult.



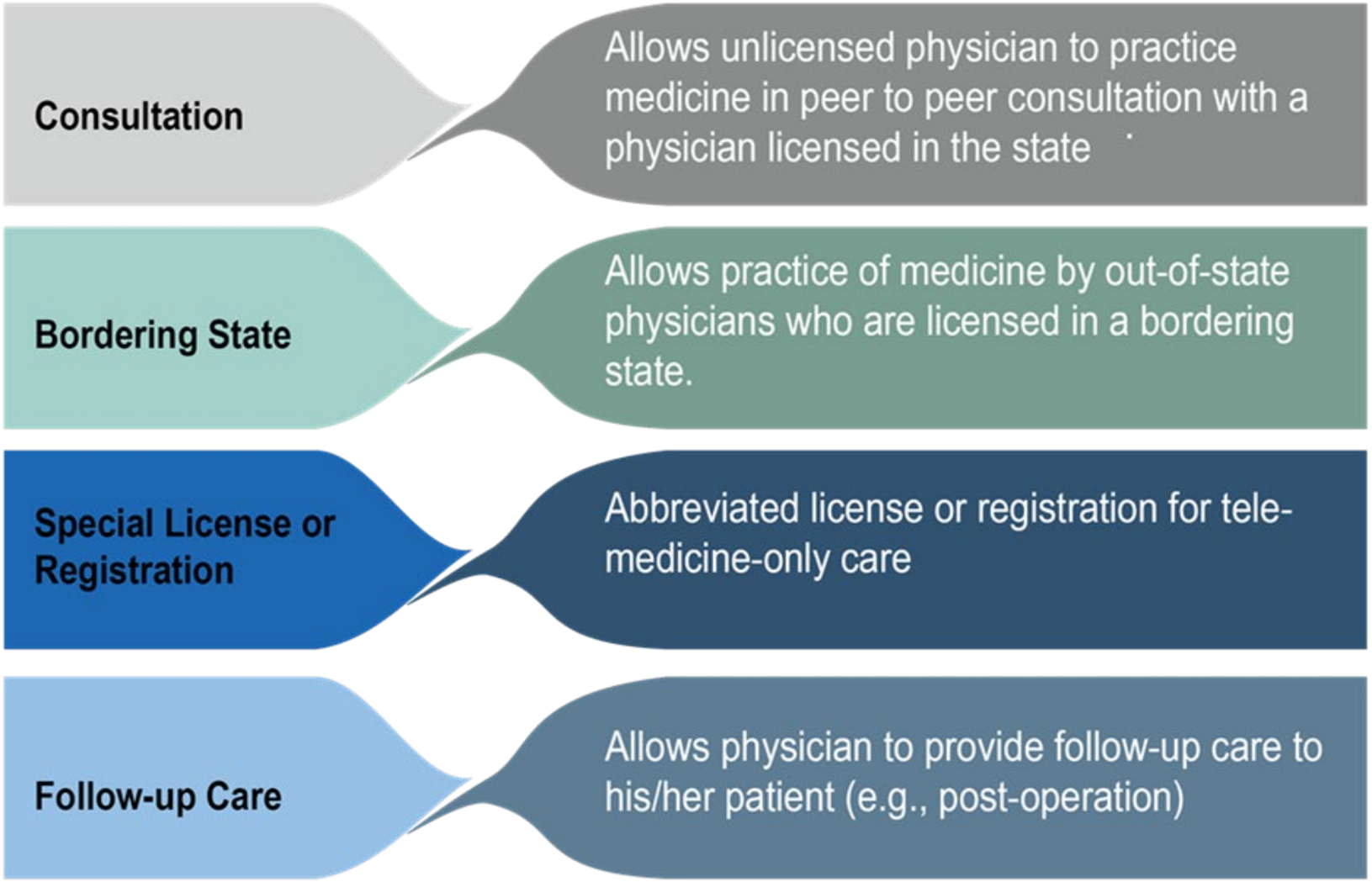
Challenges

- Maintaining licenses in multiple states is an expensive, time consuming process

- Limited portability of licenses for healthcare professionals is a significant barrier for providers, can dis-incentivize the use of telemedicine to treat patients across state lines

Physicians using telehealth technologies to provide care to patients located in California must be licensed in California.

Notable License Exceptions



Peer to Peer Consultation Exception

	Must be free	Frequency limits	No established connections or contract/ arrangement	No primary diagnosis	Limits or Restrictions on Pathology	Limits or Restrictions on Radiology	Informal/ Curbside/ No Written Opinion	No in-state office or meeting place	Expressly Doc to Doc Only	Other
DE		12 times per year							X	
DC										
KY		Infrequently			X				X	X Consulting physician cannot be a Kentucky resident
MD									X	X Consulting physician cannot be a resident of Maryland
NJ		Episodic		X	X Diagnostic tests	X Diagnostic tests		X		
NC		Irregular				X			X	X Physicians living in neighboring states excluded

CA Peer-to Peer Exception

"Nothing in this chapter applies 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, or when an invited guest of the California Medical Association or the California Podiatric Medical Association, or one of their component county societies, or of an approved medical or podiatric medical school or college for the sole purpose of engaging in professional education through lectures, clinics, or demonstrations, if he or she is, at the time of the consultation, lecture, or demonstration a licensed physician and surgeon or a licensed doctor of podiatric medicine in the state or country in which he or she resides. This practitioner 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 this state."

Cal. Bus. & Prof. Code § 2060 (Exemptions; out of state practitioners; consultations; professional education)

Growth of Interstate Licensing Compacts

Federation of STATE MEDICAL BOARDS

NLC NURSE LICENSURE COMPACT

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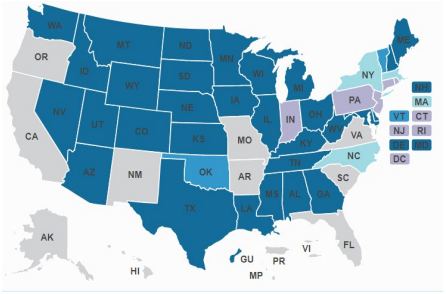

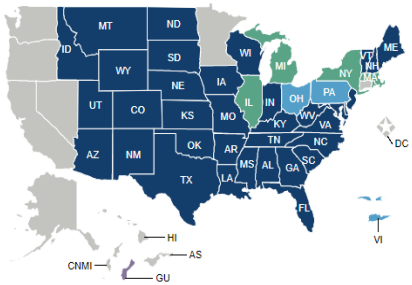

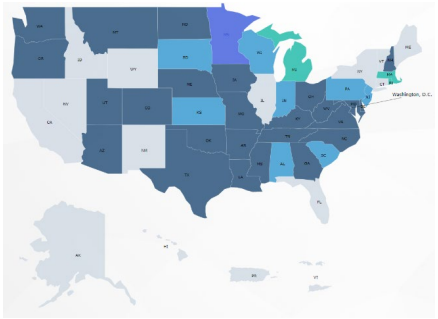

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Interstate Medical Licensure Compact

- Interstate Medical Licensure Compact (IMLC) was created in an effort to address this legal hurdle
- Voluntary agreement among the licensing boards of participating states
  - Allows physicians to practice medicine across state lines if eligibility requirements are satisfied
  - Streamlines and expedites the interstate licensure process
  - Similar licensing compacts for other provider types

CA is not a participant in the IMLC

Telemedicine State Practice Standards

1. New Patient vs. Established
2. In-Person Exam
3. Originating Site Restrictions
4. Patient-Site Telepresenter
5. Modality of Communication Technology
6. Remote Prescribing (incl. Controlled Substances)
7. Record-Keeping and Record-Sharing
8. Informed Consent
9. Patient Choice of Provider
10. Disclosures
11. Malpractice & Professional Insurance Considerations
12. Credentialing

Analyzing Telemedicine Modalities and State Law

	Modality to establish physician-patient relationship	Modality after creating valid physician-patient relationship	Modality for prescribing non-controlled substances
DE	AV: YES IA: YES S&F: NO	AV: YES IA: YES S&F: YES	AV: YES IA: YES S&F: YES
DC	AV: YES IA: YES S&F: NO	AV: YES IA: YES S&F: NO	AV: YES IA: YES S&F: NO
KY	AV: YES IA: YES S&F: YES	AV: YES IA: YES S&F: YES	AV: YES IA: YES S&F: YES
NJ	AV: YES IA: YES S&F: YES	AV: YES IA: YES S&F: YES	AV: YES IA: YES S&F: YES

CA examples

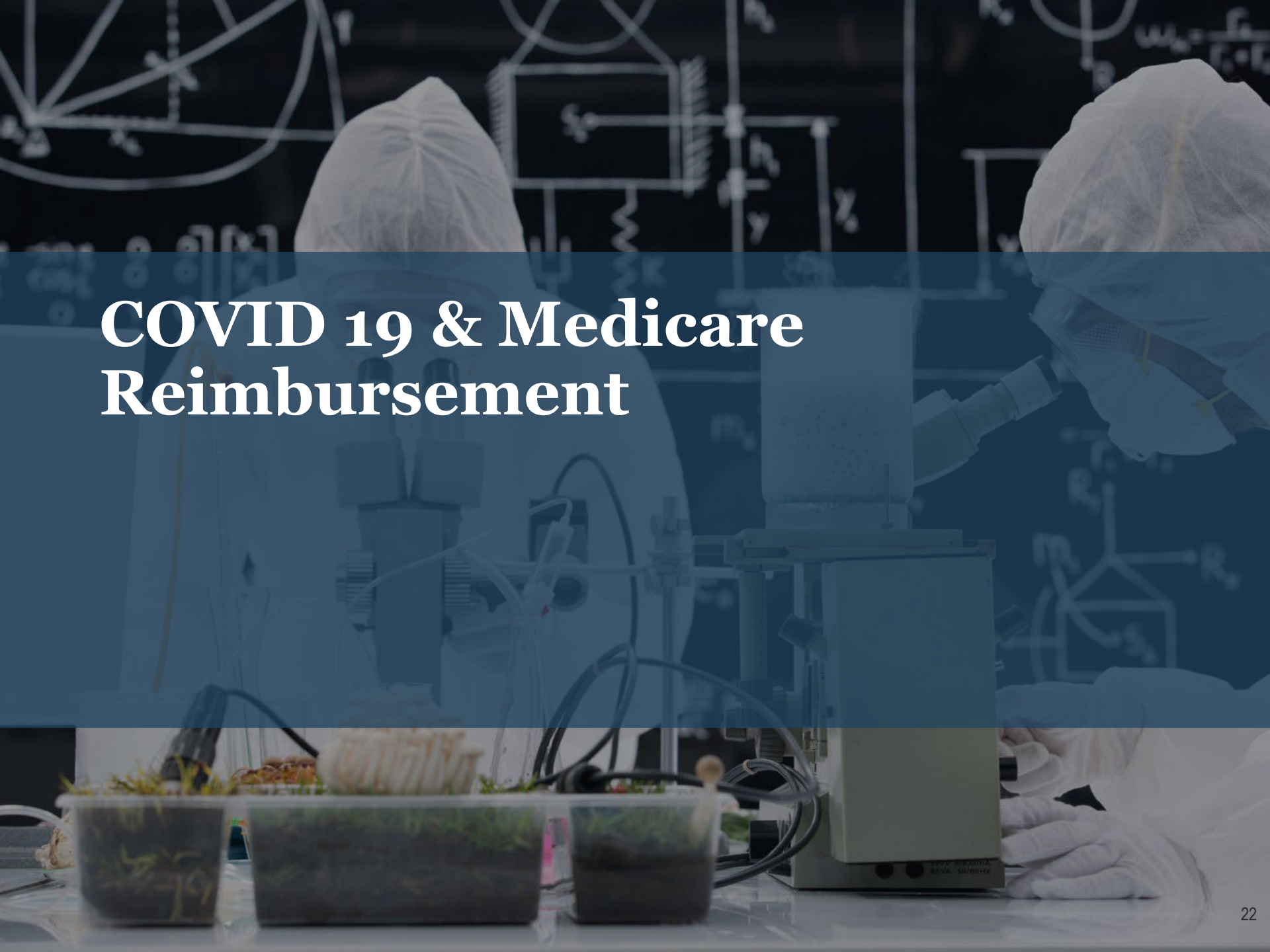
Can a valid physician-patient relationship be established via telemedicine without an in-person exam?

Yes. While California's telehealth statute, as well as medical licensure statutes and regulations, are silent as to whether a valid physician-patient relationship may be established via telemedicine without an in-person exam, the California medical board's non-binding guidance broadly endorses the use of telehealth without in-person contact.

What modality is required to establish a valid physician-patient relationship?

Silent. California's Business and Professions Code, medical board regulations, and guidance are silent and do not expressly address the modality required to establish the physician-patient relationship.

When a state law is silent on a particular telehealth practice standard issue, in this case the appropriate modality to establish a physician-patient relationship, the decision is subject to the professional discretion of the individual physician within the scope of his or her license, within clinically-accepted standards, and subject to the minimum practice standards.



COVID 19 & Medicare Reimbursement

Telehealth and Medicare – Pre-COVID-19

1. Patient in a qualifying rural area
2. Patient at qualifying facilities ("originating site")
3. Service provided by an eligible professional ("distant site practitioner")
4. Technology is real-time audio-video (interactive audio and video telecommunications system that permits real-time communication between the beneficiary and the distant site provider)
5. The service is among the list of CPT/HCPCS codes covered by Medicare

Medicare Telehealth Waivers

Location

- Removal of Geographic & Facility Requirements

Modality

- Smartphones
- Audio-only allowed

Reimbursement

- Will pay facility fee for telehealth services furnished at home at same rate as in person
- Report POS codes that would have been reported in person
- Modifier 95 applied to claims furnished via telehealth

New CPT Codes

- Added over 90 new CPT codes for telehealth services

Other

- Expanded types of professionals who can provide telehealth services
- Waived in-state licensure requirement (but state requirements still apply)
- Direct Supervision can be provided through real-time audio-video

Federal Waivers During the COVID-19 PHE

- Medicare Requirements for Telehealth
  - **Licensure:** Waived Medicare and Medicaid requirements that physicians (and NPPs) must be licensed in the state where they provide services, subject to certain conditions:
    - The provider is enrolled as such in the Medicare program.
    - The provider possesses a valid license to practice in the state that relates to his/her Medicare enrollment.
    - The provider furnishes services—whether in person or via telehealth—in a state in which the emergency is occurring in order to contribute to relief efforts in his/her professional capacity.
    - The provider is not affirmatively excluded from practice in the state or in any other state that is part of the 1135 emergency area.
  - **In-person Requirements:** Relaxed enforcement of requirement that patient have a prior established relationship with the physician (or provider at the practice) prior to furnishing of telehealth services.

Federal Waivers During the COVID-19 PHE

- Medicare Requirements for Telehealth
  - **Payment Parity**: Prior to the PHE, telehealth services were reimbursed at a lower rate than in-person services. During the PHE, telehealth services are reimbursed at the same rate as the equivalent in-person service.
  - **OIG Enforcement**: Relaxed enforcement against providers who reduce or waive cost-sharing for telehealth visits paid by federal healthcare programs.
  - **Frequency of Provision of Telehealth Services**: Waived limitations on the frequency at which certain services can be provided by telehealth
    - Subsequent inpatient visits – no frequency limits
    - Subsequent skilled nursing visits – no frequency limits
    - Critical care consult codes – may be furnished beyond the once-per-day limitation

Federal Waivers During the COVID-19 PHE

- Medicare Requirements for Telehealth
  - **Modalities**: Waived requirement of audiovisual functionality and prohibition of use of telephones for certain services.
  - Further, opioid treatment programs may conduct therapy and counseling sessions through audio-only telephone calls.

Consolidated Appropriations Act of 2023- temporary Medicare Changes

- CAA extended the following telehealth flexibilities authorized during the COVID-19 PHE through **December 31, 2024**:
  - Health care providers eligible to bill Medicare can bill for telehealth services regardless of where the patient or provider is located (i.e., the patient can be at home).
  - Audio-only telehealth visits will continue to be reimbursable.
  - The list of providers eligible to deliver telehealth services remains expanded to include physical therapists, occupational therapists, speech language pathologists, and audiologists.
  - The acute hospital care at home program can continue to be utilized to provide hospital services to patients in their homes, including through telehealth

Medicare Payment Parity

- During the pandemic the CMS initiated higher reimbursement for telehealth services at non-facilities, such as a patient's home – i.e. Medicare has been paying for telehealth services as if they were provided in-person, meaning the telehealth visits are being paid by Medicare at the same rate as regular, in-person visits.
- These higher reimbursement rates will end.
- Rates could return to lower pre-pandemic levels unless lawmakers choose to extend the policy.

Consolidated Appropriations Act of 2023 – temporary Medicare Changes

- Telehealth can be used to conduct recertification of eligibility for hospice care.
- Patients with High Deductible Health Plans coupled with Health Savings Accounts can utilize first dollar coverage for telehealth services without first having to meet their minimum deductible.
- Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) can provide telehealth services to Medicare beneficiaries (i.e., can be distant site providers), rather than being limited to being an originating site provider for telehealth (i.e., where the beneficiary is located).

The CAA also delayed the imposition of the pre-requisite in-person requirement for mental health services furnished through telehealth until after December 31, 2024

Temporary changes through the end of COVID-19

- Telehealth can be provided as an expected benefit.

- Medicare-covered providers may use any non-public facing app to communicate with patients without risking any federal penalties — even if the application isn't in compliance with HIPAA.

Permanent Medicare Changes

- FQHCs and RHCs can serve as a distant site provider for behavioral/mental telehealth services.
- Medicare patients can receive telehealth services for behavioral/mental health care in their home.
- There are no geographic restrictions for originating site for behavioral/mental telehealth services.
- Behavioral/mental telehealth services can be delivered using audio-only communication platforms.
- Rural hospital emergency department are accepted as an originating site.

End of Telehealth & RPM Copayment Waivers

- **OIG Issued Policy Statement**

Notified health care providers that they will not be subject to administrative sanctions under the federal Anti-Kickback Statute or the Civil Monetary Penalty and exclusion laws for reducing or waiving cost-sharing amounts (like copayments and deductibles) for telehealth services or remote patient monitoring (RPM) services furnished to Medicare beneficiaries during the PHE.

End of Telehealth & RPM Copayment Waivers

- The waiver is tied to the duration of the PHE.
- Unless the OIG issues additional guidance or an extension, after May 11, health care providers offering telehealth or RPM services to Medicare beneficiaries may no longer reduce or wave any cost-sharing obligations that patients may owe for such services.
- Digital health companies without payment and collection mechanisms for these payments will need to act swiftly to operationalize new process to ensure these amounts are charged and collected.

RPM Services Again Limited to "established patients"

- outside of the PHE, RPM services are limited to "established patients."
- For the duration of the PHE, CMS waived the "established patient" requirement and allowed practitioners to bill for RPM for new patients.
- Post PHE, CMS will require that RPM services be furnished only to established patients.
- Suggests that after the PHE the physician must first conduct a new patient evaluation and management service before rendering RPM to such patient.

Virtual Direct Supervision Scheduled to End This Year

- During PHE CMS waived the direct supervision rules to allow the supervising professional to be remote and use real-time, interactive audio-video technology.
- That change did not require the professional's real-time presence at, or live observation of, the service via interactive audio-video technology throughout the performance of the procedure.
- In the 2023 physician fee schedule, CMS declined to extend this temporary policy beyond the end of the calendar year in which the PHE ends --- virtual direct supervision will expire at the end of this year unless CMS revises its policy in future rulemaking.

End of HIPAA-related Enforcement Discretion

- For the duration of the PHE, the HHS Office for Civil Rights (OCR) will exercise enforcement discretion allowing providers to use telehealth in good faith even if their platforms or software did not follow HIPAA rules.
- After May 11, the OCR will resume enforcement of penalties on providers for noncompliance with HIPAA rules for technology use.
- Ahead of the end of the PHE, OCR has provided clarification on how and the circumstances under which the HIPAA rules apply to telehealth.

OCR HIPAA Guidance

Covered health care providers can use remote communication technologies to provide audio-only telehealth services when such communications are conducted in a manner that is consistent with the applicable requirements of the HIPAA Privacy, Security, and Breach Notification Rules (HIPAA Rules).

- **Does the HIPAA Privacy Rule permit covered health care providers and health plans to use remote communication technologies to provide audio-only telehealth services?**

  Yes

OCR HIPAA Guidance

- **Do covered health care providers and health plans have to meet the requirements of the HIPAA Security Rule in order to use remote communication technologies to provide audio-only telehealth services?**

Yes, in certain circumstances

The HIPAA Security Rule does not apply to audio-only telehealth services provided by a CE that is using a standard telephone line (land line). However, the HIPAA Security Rule applies when a CE uses other electronic communication technologies and mobile technologies that use electronic media, such as the Internet, intra- and extranets, cellular, and Wi-Fi. An individual receiving telehealth services may use any telephone system they choose and is not bound by the HIPAA Rules when doing so. A CE is not responsible for the privacy or security of individuals' health information once it has been received by the individual's phone or other device.

OCR HIPAA Guidance

- **Do the HIPAA Rules permit a covered health care provider or a health plan to conduct audio-only telehealth using remote communication technologies without a business associate agreement in place with the vendor?**

Yes, in some circumstances

The HIPAA Rules require a CE to enter into a BAA with a telecommunication service provider (TSP) only when the vendor is acting as a BA. A CE using a telephone to communicate with patients is not required to enter into a BAA with a TSP that has *only transient access to the PHI it transmits* because the TSP is acting merely as a conduit for the PHI. However, a BAA is needed with a TSP that is more than a mere conduit for PHI.

OCR HIPAA Guidance

- **Do the HIPAA Rules allow covered health care providers to use remote communication technologies to provide audio-only telehealth if an individual's health plan does not provide coverage or payment for those services?**

Yes

Covered health care providers may offer audio-only telehealth services using remote communication technologies consistent with the requirements of the HIPAA Rules, regardless of whether any health plan covers or pays for those services.

Telemedicine and Prescribing

Telemedicine and Prescribing

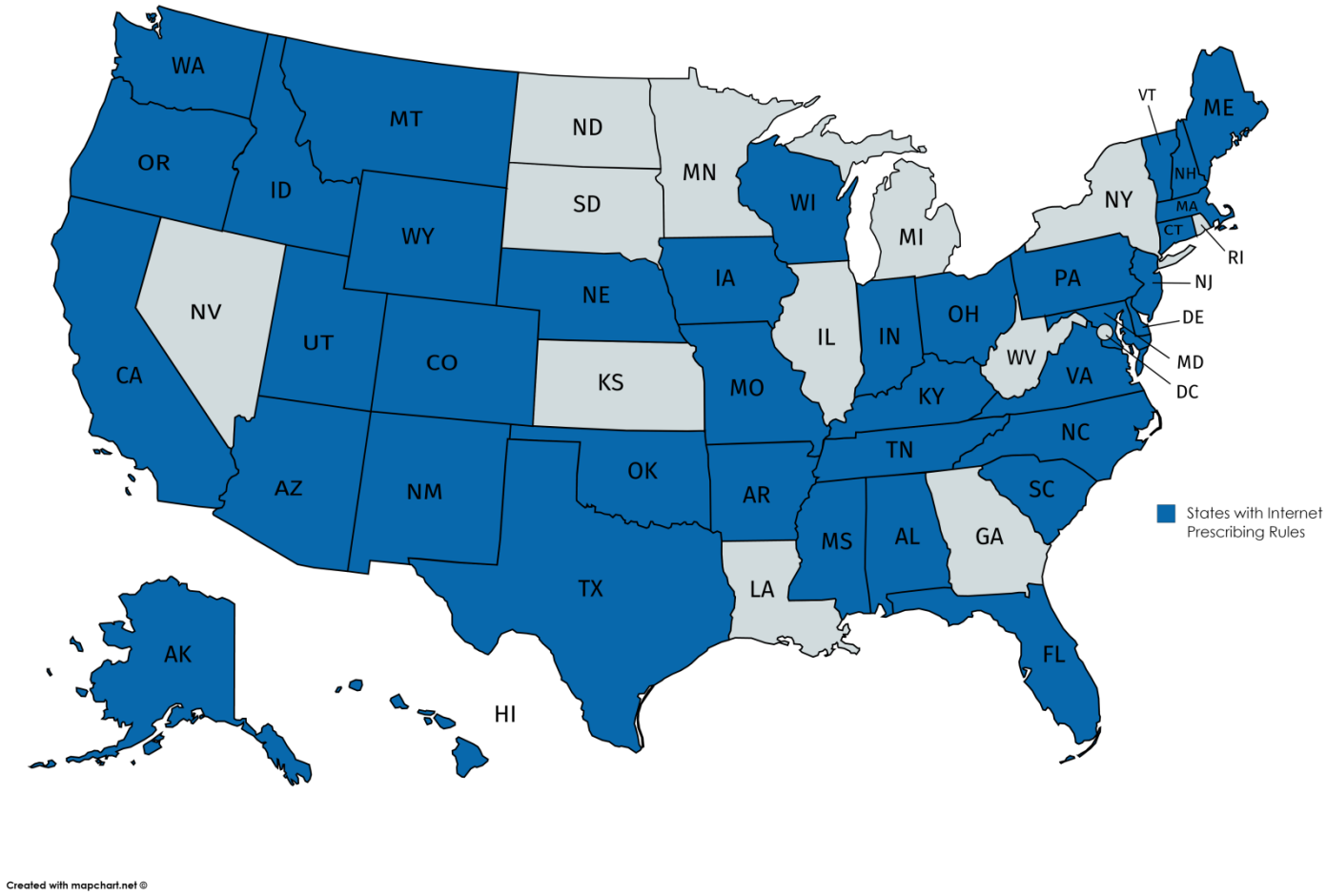
- Prescribe in connection with a provider-patient relationship
- What constitutes a valid provider-patient relationship?
- What constitutes a valid prescription?
  - Modality (state law)
  - Non-controlled substance? (state law)
  - Controlled substance? (state law)
  - Controlled substance? (federal law)

- *Not just professional board rules, but pharmacy board rules also*

Prescribing

- States take different approaches to remote prescribing
  - Some have rules specific to controlled substances and others have rules that apply to all prescription drugs
  - Some explicitly require an in-person or physical examination prior to prescribing
    - Some permit this exam to occur via telemedicine and others are unclear or silent
  - Many prohibit prescribing based solely on online questionnaire
  - Some regulate through Pharmacy laws
- **Federal Laws**
  - The Controlled Substances Act regulates the manufacture, importation, possession, use and distribution of controlled substances
    - DEA Registration, Prescribing Limitations
  - The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 State versus Federal
  - The federal regulations are stricter than many state laws or state medical board requirements

States with “Internet Prescribing Rules



California – Online Prescribing

- Prescribing, dispensing, or furnishing dangerous drugs as defined in Section 4022 without an appropriate prior examination and a medical indication, constitutes unprofessional conduct. An appropriate prior examination does not require a synchronous interaction between the patient and the licensee and can be achieved through the use of telehealth, including, but not limited to, a self-screening tool or a questionnaire, provided that the licensee complies with the appropriate standard of care.

SOURCE: CA Business & Professions Code Sec. 2242 (a). (Accessed Feb. 2023).

Controlled Substances

- Ryan Haight Act
- Federal prohibition on form-only online prescribing for controlled substances (CS)
- Per se violation of the Controlled Substances Act for a physician to prescribe a CS via the internet absent at least one in-person medical exam, except in certain, specified circumstances

Ryan Haight Act

- Does not prohibit use of telemedicine to prescribe CS if federal and state requirements are met.
- Exceptions to in-person evaluation requirement.
- Practice of telemedicine exceptions:

1. Treatment in hospital or clinic
2. Treatment in physical presence of a physician
3. **Special registration**
4. Public health emergency
5. Indian health service/tribal organization
6. Dept. of Veteran Affairs medical emergency
7. ***other circumstances specified by regulation***

COVID Waivers

- In January 2020, the DEA revised CS remote prescribing restriction were for the duration of the PHE; rolling back select provisions of the Ryan Haight Act.

- The Ryan Haight Act requires practitioners issuing a prescription for a CS to conduct an in-person medical evaluation or conduct a video/audio communication in a DEA-registered facility at a minimum of once every 24 months.

COVID Waiver

- During PHE: providers can now issue a prescription for a CS without first conducting an in-person examination, provided all of the following conditions are met:

✓ The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of their professional practice;

✓ The telemedicine communication is conducted using an audio-visual, real-time, and two-way interactive communication system; and

✓ The practitioner is acting in accordance with applicable federal and state laws.

Changes / Legislation

- **Special Registration for Telemedicine Clarification Act of 2018**

- Amends the Controlled Substances Act to establish a deadline for the Drug Enforcement Administration to promulgate regulations for the special registration of practitioners to practice telemedicine.

- Directs the AG, with the Secretary of HHS, to, within 30 days of passage of the Act, promulgate interim final regulations governing the issuance to practitioners of a special registration relating to the practice of telemedicine.

- Special registration would allow practitioners to use telemedicine to prescribe controlled substances without the *per se* in-person exam.

DEA's Proposed Rules on Telemedicine Controlled Substances Prescribing – Post PHE

- On February 24, 2023, the Drug Enforcement Agency announced ***proposed*** rules for prescribing controlled substances via telemedicine after the PHE expires.
  - DEA proposed creating 2 new limited options for telemedicine prescribing of controlled substances without a prior in-person exam. The options are complex and more restrictive than what has been allowed under the PHE waivers.
  - The proposed rules fail to include the long-awaited telemedicine special registration regulation.

DEA Proposed Rule

- The proposed rule creates a new option under exception #7 under the Ryan Haight Act (the ***other circumstances specified by regulation*** exception).
- The proposed rule is designed to ensure that patients do not experience lapses in care, and to ensure continuity of care under the current telehealth flexibilities in place as a result of the COVID-PHE.

DEA Proposed Rule – Two Options

- Option 1

A virtual first process where a practitioner can issue an initial prescription for a controlled substance without having conducted an in-person exam of the patient, but only if:

1) the medication is a non-narcotic Schedule III, IV, or V controlled substance (or buprenorphine for treatment of OUD); and
2) the prescribed amount does not exceed 30 days.

This is called a "telemedicine prescription." Before any additional prescribing can occur, the patient must undergo an in-person exam.

DEA Proposed Rule – Two Options

- Option 2

A "qualified telemedicine referral" process where a patient has an initial in-person exam with a practitioner, who subsequently refers the patient to a second practitioner.

The second practitioner can have a telemedicine exam of the patient and prescribe a controlled substance without personally conducting an in-person exam of the patient.

Under this referral process, the telemedicine practitioner can prescribe Schedule II-V and narcotic controlled substances.

DEA Proposed Rule

- Compared to the original Ryan Haight Act, these new options are expanded flexibilities intended to allow more telemedicine-based care, ***but*** are more restrictive than what has been allowed for under the PHE waivers.
- DEA's proposal will discontinue the ability for telemedicine prescribing of controlled substances where the patient never has any in-person exam (with the exception of an initial prescription period of no more than 30 days' supply).
- If the patient requires a Schedule II medication or a Schedule III-V narcotic medication (with the sole exception of buprenorphine for OUD treatment), an initial in-person exam is required *before* a prescription can be issued.

DEA Proposed Rule

- **Does the proposed rule apply to any and all telemedicine prescribing of controlled substances under the Ryan Haight Act (e.g., even if a different practice of telemedicine exception is met, or if the practitioner conducted a prior in-person exam)?**

No. The requirements in the proposed rule affect what DEA refers as "a narrow subset of telemedicine consultations." Specifically, practitioners who issue "telemedicine prescriptions" under Section 802(54)(G) – the newly-created option under the proposed rule.

DEA Proposed Rule

- **Are patients who received a telemedicine-only exam during the COVID-19 PHE "grandfathered" or must they have an in-person exam before the COVID-19 PHE ends on May 11, 2023?**

The Controlled Substances Act does not have a feature allowing patients to be "grandfathered" from the in-person exam requirement at the conclusion of a PHE. The current DEA waiver of the in-person exam requirement falls under exception #4 of the Ryan Haight Act, i.e., the PHE. It will expire when the COVID-19 PHE ends May 11, 2023.

To address this, the proposed rule creates a new term, "*telemedicinerelationship established during the COVID-19 public health emergency*." Such a relationship exists if: 1) between March 16, 2020 and May 11, 2023 (i.e., the PHE period); 2) the practitioner prescribed a controlled substance based on a telemedicine encounter; and 3) the practitioner never conducted an in-person exam of the patient.

DEA Proposed Rule

- **What is the proposed definition of "telemedicine prescription"?**

Telemedicine prescription means "a prescription issued pursuant to § 1306.31 by a physician, or a "mid-level practitioner" as defined in 21 § CFR 1300.01(b), engaging in the practice of telemedicine as defined in 21 C.F.R. § 1300.04(j)."

- **Does the proposed 180-day extension for telemedicine relationships established during the PHE apply to Schedule II controlled substances and other narcotics?**

Yes. According to the DEA's proposed rule, this allowance "applies to all schedule II-V controlled substances in all areas of the United States."

DEA Proposed Rule

- **What is the virtual first "telemedicine prescription" option under the proposed rule? How does this new process work?**

Under this proposed process, a practitioner can use telemedicine to issue an initial "*telemedicine prescription*" for a controlled substance without first conducting an in-person exam of the patient. This process works even if the practitioner cannot meet any other exception under the Ryan Haight Act or if they did not receive a qualifying telemedicine referral. The intended use case is for telemedicine-only consults with new patients.

DEA Proposed Rule

- **What is a "qualifying telemedicine referral" under the proposed rule? How does this new referral-based process work?**

A *qualifying telemedicine referral* means "a referral to a practitioner that is predicated on a medical relationship that exists between a referring practitioner and a patient where the referring practitioner has conducted at least one medical evaluation in the physical presence of the patient, without regard to whether portions of the evaluation are conducted by other practitioners, and has made the referral for a legitimate medical purpose in the ordinary course of their professional practice. A qualifying telemedicine referral must note the name and National Provider Identifier (NPI) of the practitioner to whom the patient is being referred."

OIG Fraud and Abuse Focus

OIG Special Fraud Alert 7-20-22

- The OIG published a Special Fraud Alert on arrangements with telemedicine companies, setting forth 7 characteristics OIG believes could suggest a given arrangement poses a heighted risk of fraud and abuse.
- The Alert follows dozens of civil and criminal investigations into fraud schemes involving companies that claimed to provide telehealth, telemedicine, or telemarketing services, but allegedly engaged in kickbacks and substandard medical practices to generate medically unnecessary orders and prescriptions.
- Those purported telemedicine companies, OIG stated in the Alert, “exploited the growing acceptance and use of telehealth” and present “the potential for considerable harm to Federal health care programs and their beneficiaries.”

OIG Special Fraud Alert – Suspect Characteristics

- The purported patients for whom the practitioner (clinician) orders or prescribes items or services were identified or recruited by the telemedicine company, telemarketing company, sales agent, recruiter, call center, health fair, and/or through internet, television, or social media advertising for free or low out-of-pocket cost items or services.
- The practitioner does not have sufficient contact with or information from the purported patient to meaningfully assess the medical necessity of the items or services ordered or prescribed.

OIG Special Fraud Alert – Suspect Characteristics

- The telemedicine company compensates the practitioner based on the volume of items or services ordered or prescribed, which may be characterized to the practitioner as compensation based on the number of purported medical records that the practitioner reviewed.
- The telemedicine company only furnishes items and services to Federal health care program beneficiaries and does not accept insurance from any other payer.

OIG Special Fraud Alert – Suspect Characteristics

- The telemedicine company claims to only furnish items and services to individuals who are not Federal health care program beneficiaries but may in fact bill Federal health care programs.
- The telemedicine company only furnishes one product or a single class of products (e.g., durable medical equipment, genetic testing, diabetic supplies, or various prescription creams), potentially restricting a practitioner's treating options to a predetermined course of treatment.

OIG Special Fraud Alert – Suspect Characteristics

- The telemedicine company does not expect practitioners (or another practitioner) to follow up with purported patients nor does it provide practitioners with the information required to follow up with purported patients (e.g., the telemedicine company does not require practitioners to discuss genetic testing results with each purported patient).

According to the OIG, schemes that contain these suspect characteristics can raise fraud concerns because of the potential for considerable harm to Federal health care programs and their beneficiaries.

OIG Special Fraud Alert – what comes next?

- Increased/expansion of telemedicine, the diversification in patient-payer mix, the expiration of PHE waivers, and the abatement of the pandemic will likely encourage DOJ and HHS-OIG to increase investigations of telemedicine companies and target arrangements and practices the government agencies believe are illegal.

DOJ/OIG - Enforcement

- Enforcement scrutiny will most likely arrive in the form of:

1) search warrants;
2) DEA subpoenas;
3) Grand Jury subpoenas;
4) civil investigative demands (CIDs) from DOJ in connection with False Claims Act investigations; and
5) HHS-OIG inquiries in connection with Civil Monetary Penalty and other investigations and audits.

False Claims Act data mining is thriving and companies cannot expect to fly under the radar, particularly when billing Federal healthcare programs.

Fraud Trends

- Pharmacy Fraud
- DME Orthotics and Braces
- Genetic Testing
- Identity Theft
- Excluded Individuals
- Schemes Moving to Medicare Advanta
- Impact of Direct Contracting

NATIONWIDE BRACE SCAM

Scammers are contacting Medicare beneficiaries to offer "free or low-cost" orthotic braces. These fraudsters bill Medicare for medically unnecessary equipment using beneficiaries' information. All beneficiaries across the country are potential targets in this scheme.

Learn More: oig.hhs.gov/bracescam

Report Fraud: **1-800-HHS-TIPS** or oig.hhs.gov/fraud/hotline

U.S. Department of Health and Human Services
Office of Inspector General

The **Alleged Scheme** and **Key Players**

Conspirators

They own a call center that airs television and radio advertisements for orthotic braces paid for by Medicare. Telemarketers call beneficiaries directly to offer "free or low-cost" orthotic braces.

! They are the masterminds of this scheme.

Call Center

The call center confirms that the beneficiaries are on Medicare and transfers beneficiaries to a telemedicine firm for a doctor's consultation.

! The call center pays the telemedicine firm and its doctor for the prescriptions.

Doctor & Telemedicine Company

Regardless of medical necessity, the doctor prescribes an orthotic brace. The telemedicine company submits the brace prescription to the call center.

! The telemedicine company and doctor generate prescriptions to keep this scheme running–not because the beneficiary needs the brace.

Call Center

The call center collects the prescriptions and sells them to the medical equipment company.

! Providers should send prescriptions to a medical equipment company because beneficiaries have medical needs for products. Prescriptions should never be sold.

Medical Equipment Company

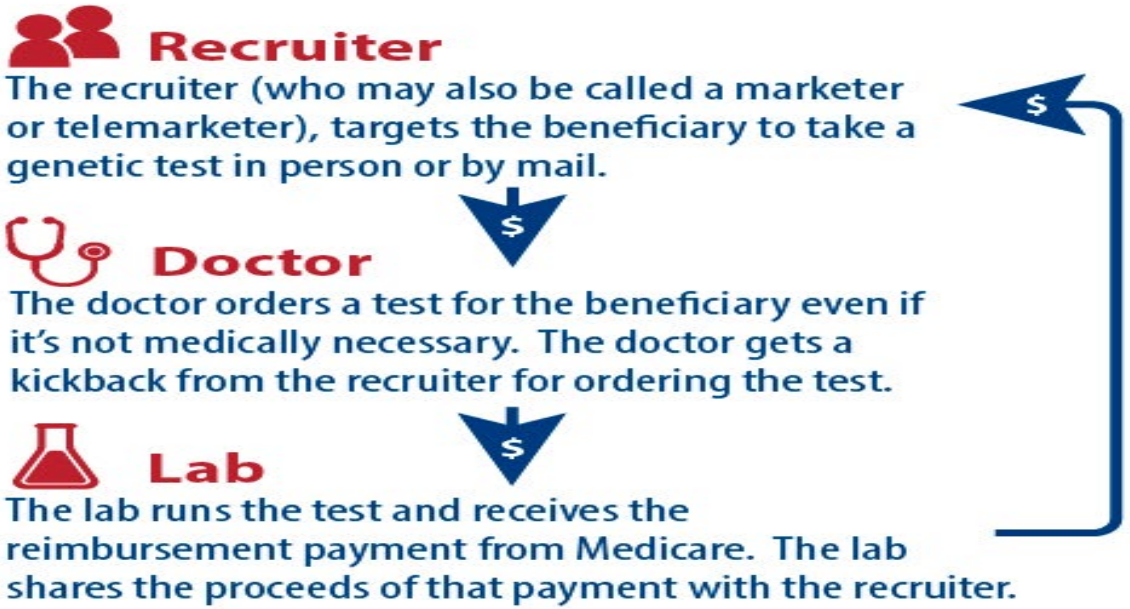
After the medical equipment company buys the prescriptions, the medical equipment company sends the brace, or multiple braces, to beneficiaries. The company bills Medicare and pays a kickback to the consipirators.

! The medical equipment company receives $500-$900 per brace from Medicare and pays the conspirators a kickback of almost $300 per brace.

* This alleged scheme is current as of April 2019.

Genetic Testing SCAM

Scammers are offering Medicare beneficiaries "free" genetic testing or cheek swabs in order to obtain beneficiaries' personal information for fraudulent purposes.



The alleged scheme is current as of September 2019.

Learn More: oig.hhs.gov/geneticscam
Report Fraud: 1-800-HHS-TIPS or oig.hhs.gov/fraud/hotline

U.S. Department of Health and Human Services
Office of Inspector General

Legal & Regulatory Considerations

U.S. Federal

- Anti-Kickback Statute
- Physician Self-Referral
- Civil Monetary Penalty Law
- Payer Rules (including Medicare, Medicaid)
- FTC, FDA, DEA
- HIPAA

U.S. State

- Patient Brokering Acts
- Fee-Splitting Laws
- Self-Referral Laws
- Corporate Practice of Medicine
- Insurance Laws
- Supervision of NPPs
- eCommerce Considerations

International

- Foreign Corrupt Practices Act
- US Export Control Laws
- US Anti-Terrorism Laws
- US Anti-Boycott Laws
- International Corporate Laws and Tax
- Data protection; data ownership; data sharing
- Intellectual Property
- GDPR

Virtual Clinical Trials

Virtual Trial Regulatory Considerations

Research is defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. 45 C.F.R. § 46.102(d).

Clinical investigation means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA . . . or the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. 21 C.F.R. § 50.3(c).

FDA considers "clinical investigation" to be synonymous with "research"

Virtual Trial Regulatory Considerations

- Increased use due to COVID – but….

Virtual trials are not new…

Pfizer conducted a “virtual” clinical trial in 2011 (tolterodine ER 4mg)

The REMOTE trial is the first entirely web-based trial conducted under an IND application. The efficacy observed was consistent with results from conventional trials. With simplification of multi-step screening and testing, web-based trials or their component parts should provide a participant friendly approach to many clinical trials.

ClinicalTrials.gov NCT01302938

Virtual Trial Regulatory Considerations

- State and Federal Telemedicine Regulations apply in addition to FDA regulations and the Common Rule.
- Consider:
  - Licensure
  - Practice Standards
  - Modalities
  - Informed Consent
  - Prescribing
  - In-Person exam requirements


QUESTIONS?

Thank You

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Upcoming CTRC Events

NCTRC Webinar - Social Determinants of Health and Value-Based Pay

April 20th @ 11 AM Pacific Time

Description: Value-Based Pay efforts are increasingly acknowledging the importance of patient social complexity in addition to a traditional focus on clinical complexity and utilization. This webinar will discuss how social determinants of health screening and action by providers are being measured and tied into payer and health system approaches in order to drive equity and sustainability in their programs.

Presented by: Ned Mossman, MPH - Director, Social, and Community Health at OCHIN, Inc

www.caltrc.org

Virtual CA 2023 Telehealth Summit: The Future is Now – What's Next for CA? is happening on June 13-14, 2023!

Thank **You**

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