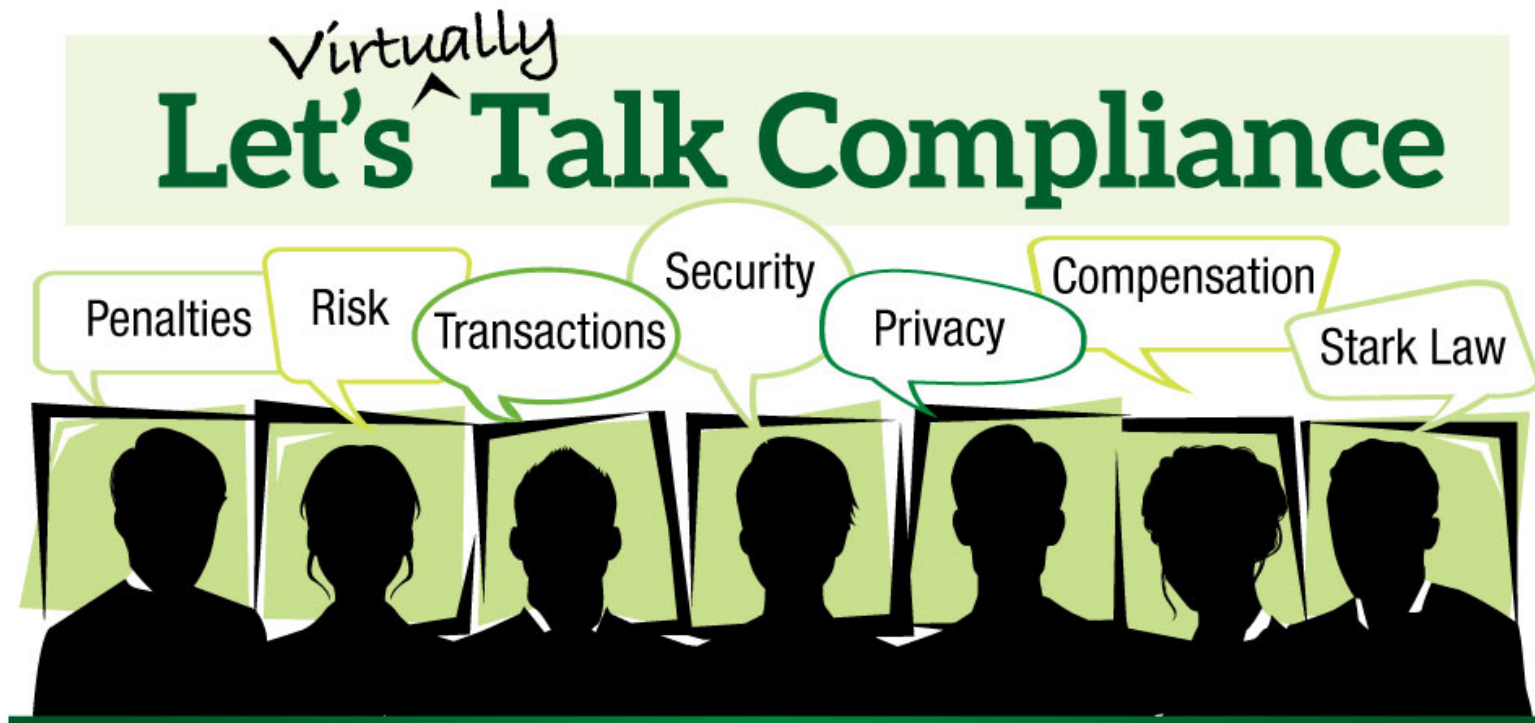


Let's Talk Compliance

One-Day Compliance Master Class



A group of business professionals are gathered around a wooden table in a meeting. A man in a dark suit and tie is pointing at a document on the table with a pen. A woman with glasses and long hair is looking at the document. Other people are visible in the background, some looking at laptops. There are coffee cups and a teapot on the table.

SESSION #3

Telemedicine: Trendy or Here to Stay?

Jackie Acosta & Valerie Rock

Disclaimer

This webinar should not be construed as legal advice on any specific facts or circumstances.

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The views set forth herein are the personal views of the authors and do not necessarily reflect those of their respective employers.



Agenda

- Telemedicine history: pre-COVID
- Current trends in telemedicine during COVID
- Anticipated future state of telemedicine post-COVID

Before the COVID-19 PHE

■ Section 1834(m)

1. **Geographic** – Patient must reside in rural area
2. **Location** – Patient must be physically present at healthcare facility when service is provided (facility fee)
3. **Service** – Coverage limited to CMS' list of approved telehealth services (CPT and HCPCS codes)
4. **Provider** – Service must be provided by physician, non-physician practitioner, clinical psychologist, clinical social worker, registered dietitian, or nutrition professional
5. **Technology** – Must utilize telecommunications technology with audio *and* video capabilities that permits real-time interactive communication.

Before the COVID-19 PHE

■ **With Some Exceptions:**

- **Telestroke** – Effective 01/01/2019, geographic and location requirements do not apply to services furnished to diagnose, evaluate, or treat symptoms of acute stroke
- **Substance Use Disorder** – Effective 07/01/2019, geographic and location requirements do not apply to services relating to SUD and co-occurring behavioral health conditions
- **ESRD** – Effective 01/01/2019, geographic and location requirements do not apply to ESRD services relating to home dialysis
- **Medicare Advantage** – For 2020 plan year, MA plan may eliminate geographic and location requirements
- **Medicare Shared Savings Program** – Waiver of geographic and location requirements for ACO participants in risk models
- **CMMI Initiatives**



COVID-19 Telehealth Coverage Expansion

■ Section 1135 Waiver

- Coronavirus Preparedness and Response Supplemental Appropriations Act expands Secretary's authority to waive *geographic* and *location restrictions* for duration of COVID-19 PHE

■ CMS Interim Final Rules

- Suspends certain *service restrictions* for duration of COVID-19 PHE
 - Expands list of covered services
 - Eliminates frequency requirements
 - Permits use of telehealth for required face-to-face visits, direct supervision for incident-to billing, teaching physician virtual presence
- Suspends certain *provider restrictions* for duration of COVID-19 PHE
 - Permits therapists and S/L pathologists to provide covered services via telehealth
 - Waives state licensure requirement
- Authorizes payment for certain audio-only E/M services



COVID-19 Telehealth Expansion

- **Agency Notices of Enforcement Discretion**

- OCR - Will not impose penalties if, in good faith, use any non-public remote audio/visual communication product for duration of COVID-19 PHE
- OIG – Permits waiver of co-insurance

- **Consolidated Appropriations Act (December 21, 2020)**

- FCC COVID-19 Telehealth Program (SEC.903 CARES Act)
- Section 123: Expanding Access to Mental Health Services Furnished Through Telehealth
- Section 313: Expanding Capacity for Health Outcomes



Press release

Trump Administration Finalizes Permanent Expansion of Medicare Telehealth Services and Improved Payment for Time Doctors Spend with Patients

Dec 01, 2020 | Physicians, Policy, Telehealth

“During the COVID-19 pandemic, actions by the Trump Administration have unleashed an explosion in telehealth innovation, and we’re now moving to make many of these changes permanent,” said HHS Secretary Alex Azar. “Medicare beneficiaries will now be able to receive dozens of new services via telehealth, and we’ll keep exploring ways to deliver Americans access to healthcare in the setting that they and their doctor decide makes sense for them.”

“Telehealth has long been a priority for the Trump Administration, which is why we started paying for short virtual visits in rural areas long before the pandemic struck,” said CMS Administrator Seema Verma. “But the pandemic accentuated just how transformative it could be, and several months in, it’s clear that the healthcare system has adapted seamlessly to a historic telehealth expansion that inaugurates a new era in healthcare delivery.”



Source: <https://www.cms.gov/newsroom/press-releases/trump-administration-finalizes-permanent-expansion-medicare-telehealth-services-and-improved-payment>

2021 Final Rule

▪ New Permanent Covered Services

<p>1. Services we are finalizing for permanent addition as Medicare Telehealth Services</p>	<ul style="list-style-type: none">• Group Psychotherapy (CPT 90853)• Domiciliary, Rest Home, or Custodial Care services, Established patients (CPT 99334-99335)• Home Visits, Established Patient (CPT 99347- 99348)• Cognitive Assessment and Care Planning Services (CPT 99483)• Visit Complexity Inherent to Certain Office/Outpatient E/Ms (HCPCS G2211)• Prolonged Services (HCPCS G2212)• Psychological and Neuropsychological Testing (CPT 96121)
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2021 Final Rule

■ Covered Services Through 12/31 of Year PHE Ends

2. Services we are finalizing to remain temporarily on the Medicare telehealth list through the end of the year in which the PHE for COVID-19 ends (Category 3 services), to allow for continued development of evidence to demonstrate clinical benefit and facilitate post-PHE care transitions.

- Domiciliary, Rest Home, or Custodial Care services, Established patients (CPT 99336-99337)
- Home Visits, Established Patient (CPT 99349-99350)
- Emergency Department Visits, Levels 1-5 (CPT 99281-99285)*
- Nursing facilities discharge day management (CPT 99315-99316)
- Psychological and Neuropsychological Testing (CPT 96130- 96133; CPT 96136- 96139)
- Therapy Services, Physical and Occupational Therapy, All levels (CPT 97161- 97168; CPT 97110, 97112, 97116, 97535, 97750, 97755, 97760, 97761, 92521- 92524, 92507)*
- and Hospital discharge day management (CPT 99238- 99239)*
- Inpatient Neonatal and Pediatric Critical Care, Subsequent (CPT 99469, 99472, 99476)*
- Continuing Neonatal Intensive Care Services (CPT 99478- 99480)*
- Critical Care Services (CPT 99291-99292)*
- End-Stage Renal Disease Monthly Capitation Payment codes (CPT 90952, 90953, 90956, 90959, and 90962)*
- Subsequent Observation and Observation Discharge Day Management (CPT 99217; CPT 99224- 99226)*



Source: CMS-1734-F, Medicare Physician Fee Schedule, Table 16 Summary of CY 2021 Services Added to the Medicare Telehealth Services List, version for public inspection, p.157

2021 Final Rule

■ Covered Services Through End of PHE

<p>3. Services we are not adding to the Medicare telehealth list either permanently or temporarily.</p>	<ul style="list-style-type: none">• Initial Nursing Facility Visits, All Levels (Low, Moderate, and High Complexity) (CPT 99304-99306)• Initial hospital care (CPT 99221-99223)• Radiation Treatment Management Services (CPT 77427)• Domiciliary, Rest Home, or Custodial Care services, New (CPT 99324- 99328)• Home Visits, New Patient, all levels (CPT 99341- 99345)• Inpatient Neonatal and Pediatric Critical Care, Initial (CPT 99468, 99471, 99475, 99477)• Initial Neonatal Intensive Care Services (CPT 99477)• Initial Observation and Observation Discharge Day Management (CPT 99218 – 99220; CPT 99234- 99236)• Medical Nutrition Therapy (CPT G0271)
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Source: CMS-1734-F, Medicare Physician Fee Schedule, Table 16 Summary of CY 2021 Services Added to the Medicare Telehealth Services List, version for public inspection, p.157

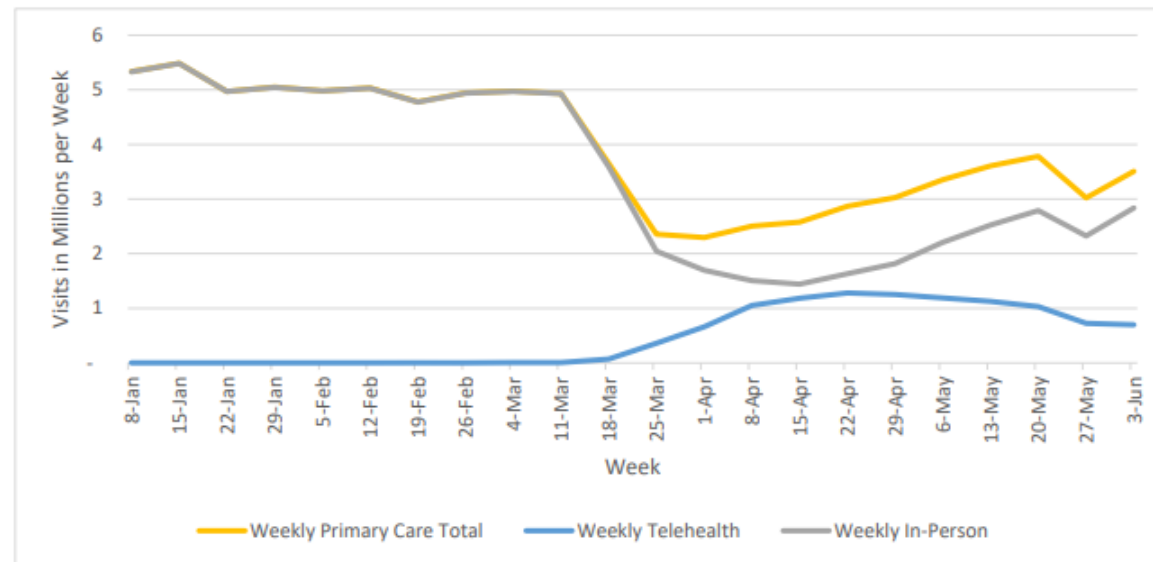
2021 Final Rule

■ Other Telehealth Provisions

- Subsequent SNF visits limited to once every 14 days (down from 30); inpatient and critical care remain once every 3 days
- Teaching physician present via telehealth for telehealth services furnished at residency training site outside MSA (plus changes to primary care exception)
- Direct supervision via telehealth for incident-to billing for telehealth services
- Direct supervision via telehealth for incident-to billing for in-person services continues through 12/31 of year in which PHE ends

MEDICARE BENEFICIARY USE OF TELEHEALTH VISITS: EARLY DATA FROM THE START OF THE COVID-19 PANDEMIC

Figure 1. Primary Care Visits for FFS Medicare Beneficiaries (visits in millions per week)



Source: Medicare claims data up to June 3rd, available as of June 16.



State Licensing and Telemedicine
(pre- and post-COVID)

Road Map

- Licensing (*pre-COVID*)
- Overview of Telemedicine Practice Standards (*pre-COVID*)
- Florida Telemedicine Practice Standards (*pre-COVID*)
- Prescribing Controlled Substances via Telemedicine under Federal Law (*pre-COVID*)
- COVID-19 Waivers

Licensure – General Requirements *(pre-COVID)*

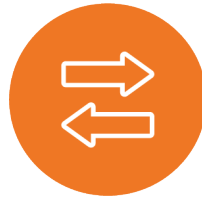
- Provider (physician, NP, PA, etc.) offering care via telemedicine is subject to licensure rules of the state in which the patient is physically located at the time of the consult.
- State law expressly or implicitly requires licensure if the patient is located in the state at the time of the consult.

Notable Exceptions for Telehealth



Consultation

Allows unlicensed physician to practice medicine in peer to peer consultation with a physician licensed in the state.



Bordering State

Allows practice of medicine by out-of-state physicians who are licensed in a bordering state.



Special License or Registration

Abbreviated license or registration for telemedicine-only care.



Follow-up Care

Allows physician to provide follow-up care to his/her patient (e.g., post-operation).

Example - Florida Consultation Exception



Consultation

- “Any physician lawfully licensed in another state or territory or foreign country, when meeting duly licensed physicians of this state in consultation.”
 - Fla. Stat. Ann. § 458.303(1)(b)

Florida Consultation Exception



Consultation

- “The term ‘consultation,’ as used in section 458.303(1)(b), F.S., encompasses the actions of a physician lawfully licensed in another state, territory or foreign country. Such physician is permitted to examine the patient, take a history and physical, review laboratory tests and x-rays, and make recommendations to a physician duly licensed in this state with regard to diagnosis and treatment of the patient. However, the term ‘consultation’ does not include such physician’s performance of any medical procedure on or the rendering of treatment to the patient.”
 - Fla. Admin. Code Ann. r. 64B8-2.001(5).

Example – Maryland Bordering State Exception



**Bordering
State**

- “A physician who resides in and is authorized to practice medicine by any state adjoining this State and whose practice extends into this State, if: (i) The physician does not have an office or other regularly appointed place in this State to meet patients; and (ii) The same privileges are extended to licensed physicians of this State by the adjoining state.”
 - Md. Health Occ. Code Ann. § 14-302(a)(4).

Example - Florida Telehealth Registration



Special License or Registration

- **“Registration of out-of-state telehealth providers**
 - (a) A health care professional not licensed in this state may provide health care services to a patient located in this state using telehealth if the health care professional registers with the applicable board, or the department if there is no board, and provides health care services within the applicable scope of practice established by Florida law or rule.”
 - Fla. Stat. Ann. § 456.47(4).

Florida Telehealth Registration



Special License or Registration

- Florida licensees can already provide telehealth services to patients in Florida that they can treat in person. No additional registration or certification is required. The out-of-state telehealth provider registration only applies to health care practitioners who are not licensed in Florida and are licensed in another state, the District of Columbia, or a possession or territory of the United States. If a Florida licensee would like to provide telehealth services to a patient outside of Florida, they must review the laws and rules in the location of the patient.
 - Florida Telehealth FAQs:
<https://www.flhealthsource.gov/telehealth/faqs>

Example – Indiana Follow-up Care Exception



Follow-up Care

- “[A] nonresident physician who is located outside of Indiana does not practice medicine or osteopathy in Indiana by providing a second opinion to a licensee *or diagnostic or treatment services to a patient in Indiana following medical care originally provided to the patient while outside Indiana.*”
 - Ind.Code Ann. § 25-22.5-1-1.1(4).

A person wearing a white lab coat is holding a tablet computer. The tablet screen is dark and appears to be displaying a video call or a document. The person's hands are visible, and they are interacting with the device. A semi-transparent blue overlay covers the middle portion of the image, containing the text.

Telemedicine Practice Standards (*pre-COVID*)

Telemedicine Practice Standards

1

Establishing Physician-Patient Relationship

5

Remote Prescribing (Non-Controlled Substances)

9

Sharing Provider's Credentials and Contact Information

2

Modality of Communication Technology

6

Remote Prescribing (Controlled Substances)

10

Special Telehealth Disclosures

3

Originating Site Restrictions

7

Medical Record-Keeping and Record-Sharing

11

Verifying the Patient's Identity and Location

4

Patient-Site Telepresenter

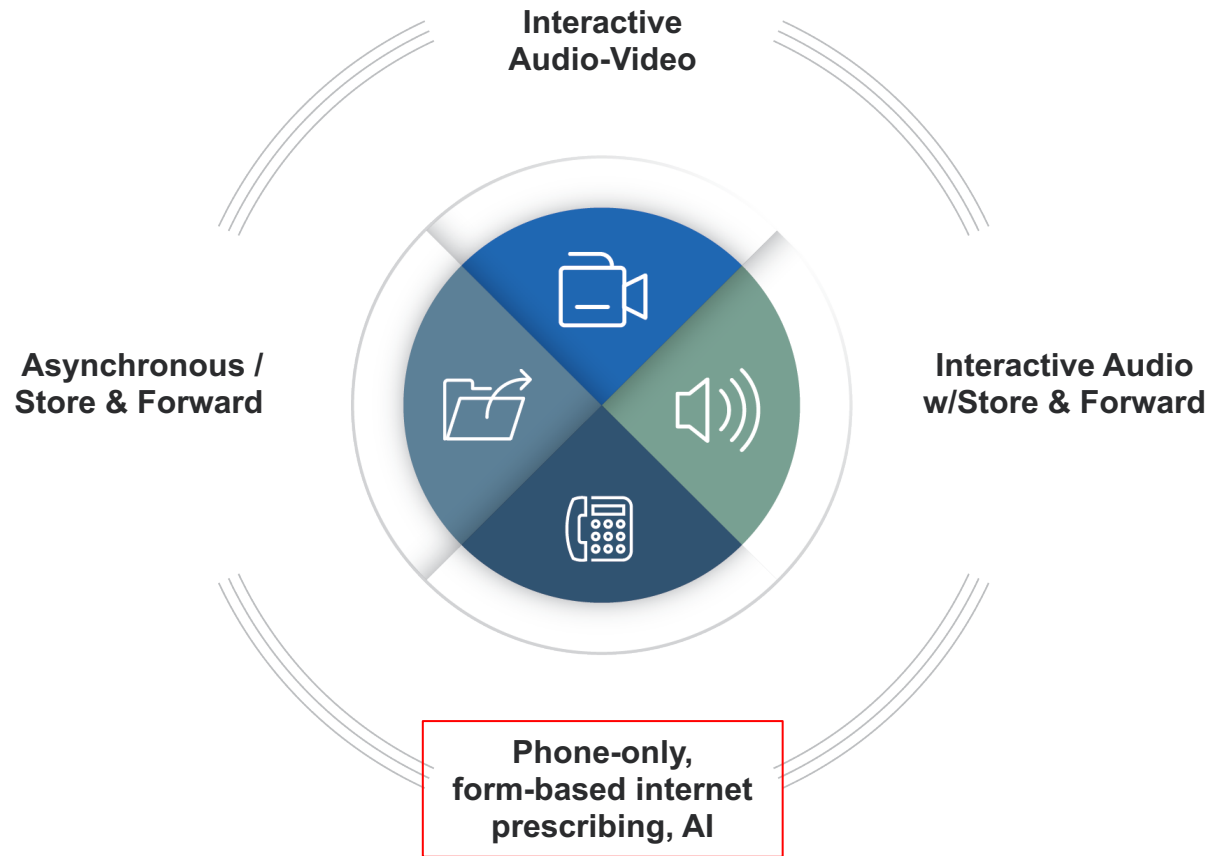
8

Telehealth Informed Consent

12

Referrals for Emergency Services and/or Follow-up Care

Telemedicine and Evolving Modalities



A person is holding a tablet computer. The screen of the tablet is dark and appears to be displaying a video call or a document. The person's hands are visible, and they are wearing a blue shirt. The background is blurred, showing what looks like a white wall and some papers. A semi-transparent blue overlay covers the middle of the image, and the text is written in white on this overlay.

Florida Telemedicine Practice Standards (pre-COVID)

Florida Telemedicine Practice Standards

1

Establishing
Physician-Patient
Relationship

- A telehealth provider has the **duty** to practice in a manner **consistent with his or her scope of practice** and the **prevailing professional standard** of practice for a health care professional who provides **in-person** health care services to patients in this state.
- If a telehealth provider conducts a patient evaluation sufficient to diagnose and treat the patient, the telehealth provider is **not required to research a patient's medical history or conduct a physical examination of the patient** before using telehealth to provide health care services to the patient.
- **Fla. Stat. Ann. § 456.47(2)(a)-(b)**

Florida Telemedicine Practice Standards

2

Modality of Communication Technology

- “Telehealth” means the use of **synchronous** or **asynchronous** telecommunications technology by a telehealth provider to provide health care services, including, but not limited to, assessment, diagnosis, consultation, treatment, and monitoring of a patient; transfer of medical data; patient and professional health-related education; public health services; and health administration.
- The term ***does not include*** audio-only telephone calls, e-mail messages, or facsimile transmissions.
- **Fla. Stat. Ann. § 456.47(1)(a)**

Florida Telemedicine Practice Standards

5

Remote Prescribing (Non-Controlled Substances)

- Can prescribe non-controlled substances via telehealth if provider performs a sufficient evaluation, if prescribing is within his/her scope of practice, and prescribing is consistent with the standard of care.
- **Fla. Stat. Ann. § 456.47**
- *Per Se Ban:*
 - **Weight Loss Drugs:** Florida also has specific in-person requirements for prescribing weight loss drugs.
 - Fla. Admin. Code r. 64B8-9.012 (5), (6), (applying to MDs); see *also* Fla. Admin. Code r. 64B15-14.004 (4), (5) (applying to DOs)

Florida Telemedicine Practice Standards

6

Remote
Prescribing
(Controlled
Substances)

- A telehealth provider may not use telehealth to prescribe a ***controlled substance unless*** the controlled substance is prescribed for the following:
 1. The treatment of a psychiatric disorder;
 2. Inpatient treatment at a hospital licensed;
 3. The treatment of a patient receiving hospice services (NEW*); **or**
 4. The treatment of a resident of a nursing home facility (NEW*)
- **Fla. Stat. Ann. § 456.47**
- *Per Se Ban:*
 - **Medical Marijuana:** A qualified physician cannot certify a qualified patient for medical marijuana via telemedicine.
 - Fla. Stat. Ann. § 381.986(4)(a)(1).

*Note: Controlled
Substances and the
Federal Ryan Haight Act*

Florida Telemedicine Practice Standards

7

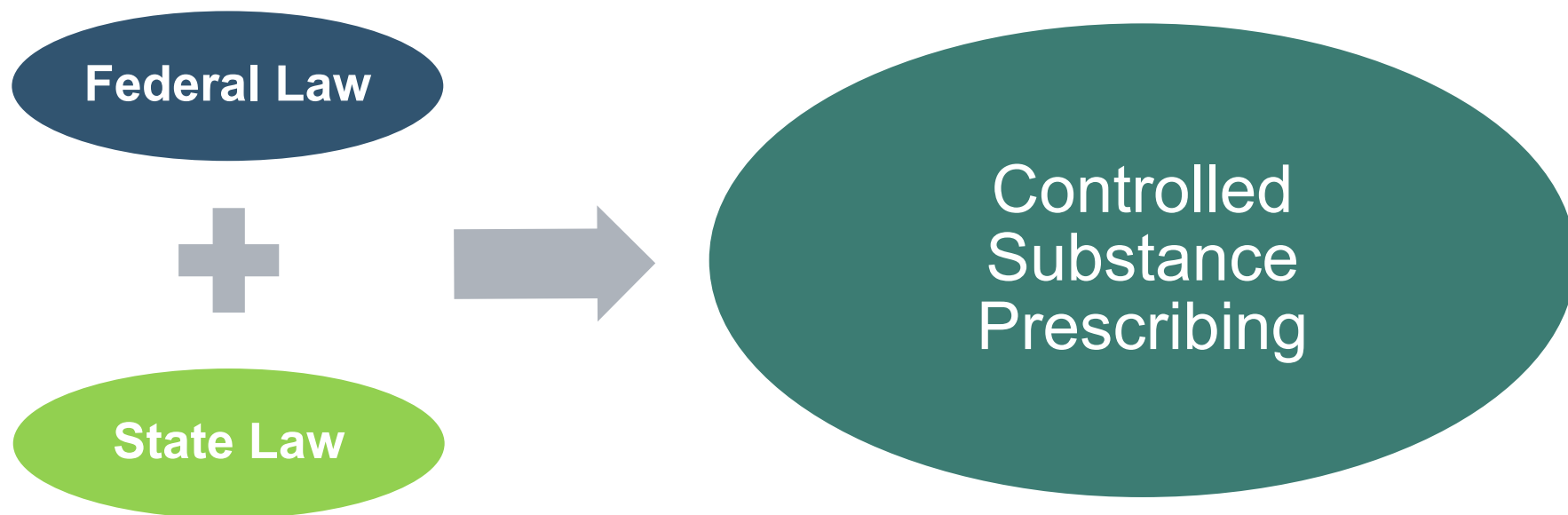
Medical Record-
Keeping and
Record-Sharing

- Telehealth providers must use the same standard of maintaining ***patient medical records*** as used for in-person services.
- They must also keep medical records confidential, as required in ss. 395.3025(4), F.S.



Prescribing Controlled Substances Via
Telemedicine Under Federal Law
(*pre-COVID*)

Controlled Substance Prescribing Via Telemedicine



Ryan Haight Act: 21 U.S.C. 829(e)

- Typically requires a prior in-person examination in order to issue a “valid prescription” for a controlled substance
- *“The term “valid prescription” means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by: 1) a practitioner who has conducted at least one in-person medical evaluation of the patient; or 2) a covering practitioner.”*
- 21 U.S.C. § 829(e)

Ryan Haight Act: 21 U.S.C. 829(e)

- Regulations offer seven “telemedicine” exceptions to the in-person exam requirement.
- **Most common** exceptions:
 1. Patient is being treated by, and physically located in, a DEA-registered hospital or clinic
 2. Treatment in the physical presence of a DEA-registered practitioner
 3. 21 C.F.R. § 1300.04(i)



COVID-19 Waivers

COVID-19 Waivers

- Waivers on the state and federal level during the PHE
 - **State:**
 - Telehealth Prescribing, Licensure Exemptions, etc.
 - **Federal:**
 - CSA: Ryan Haight Act Emergency Exception – 21 U.S.C. 829(e)

Florida– Licensing Waiver

COVID Waiver

- Florida governor declared a state of emergency in Florida.
 - See [EO No. 20-52](#) (Mar. 9, 2020).
- Florida’s Department of Health issued an Emergency Order allowing certain out-of-state health care professionals, including physicians, to temporarily provide telehealth services to persons in Florida.
 - See [DOH No. 20-002](#) (Mar. 16, 2020).
- The waiver is coterminous with the Florida governor’s declared state of emergency, including any extensions thereof.
 - See [DOH No. 20-11](#) § 2 (June 2020).
- The state of emergency was most recently extended by [EO 20-316](#) to February 27, 2021.



Federal Ryan Haight Act – COVID Waivers

Pre-COVID

- **Ryan Haight Act: 21 U.S.C. 829(e)**
 - Requires a prior in-person examination in order to issue a “valid prescription” for a controlled substance
 - Exceptions

COVID Waivers

- **Public Health Emergency Exception 42 U.S.C. 247d (Jan. 31, 2020)**
 - Prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice
 - Audio-visual, real-time, two-way interactive communication system
 - Practitioner is acting in accordance with applicable federal and state laws

Issues Relating to COVID Waivers

- Duration
- Limited Scope
 - Not full waiver of all practice standards



The Future of Telemedicine?

Ending with the End of the PHE

Reimbursement for audio-only E/M services (i.e., CPT 99441-32; 98966-68)

Reimbursement for telehealth services furnished by therapists and S/L pathologists

RHC and FQHC reimbursement for telehealth services under G2025

Reimbursement for virtual check-ins and e-visits for new patients; waiver of cost-sharing for these services

Waiver of requirement to be licensed in state in which patient receiving telehealth services is located



The Future is Dependent on Barriers

- **Expansion environment** – Increased need with decreased requirements
- **Location** – Rural to All?
- **Security** – Open or narrowed?
- **Government involvement** – Reestablished or continue to provide latitude?

Thank you.

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Jacqueline is a graduate of the University of Florida Levin College of Law (J.D., *cum laude*, 2009). While there, she received a book award in contracts, was on the dean's list and was a commissioner of the University of Florida Student Constitutional Review Committee. She earned her undergraduate degree from the University of Florida (B.S.B.A., *cum laude*, 2005), where she was a Florida Bright Future Scholar and received the President's Award.





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