

# **Telehealth Regulations: Head Off Paying Triple Damages and OIG Fines**

Presented by:  
**Anne Brendel, Esq.**

[DISCLAIMER]

© Training Leader. This 2021 Webinar Handout is published by Healthcare Training Leader, a division of Must Have Info, Inc. Reproduction or further distribution by any means, beyond the paid customer, is strictly forbidden without written consent of Training Leader, including photocopying and digital, electronic, and/or Web distribution, dissemination, storage, or retrieval.

This webinar is an independent product of Healthcare Training Leader. It is not endorsed by nor has it any official connection with any other organization, insurance carrier, vendor, or company. Reasonable attempts have been made to provide accuracy in the content. However, of necessity, examples cited and advice given in a national periodical such as this must be general in nature and may not apply to any particular case. The publisher, editors, board members, contributors, nor consultants warrant or guarantee that the information contained herein on coding or compliance will be applicable or appropriate in any particular situation.

(c) 2021 Must Have Info, Inc. All Rights Reserved.  
Healthcare Training Leader®, 2277 Trade Center Way,  
Suite 101, Naples, FL 34109, Phone: 800-767-1181 •  
Fax: 800-767-9706 • E-mail: [info@trainingleader.com](mailto:info@trainingleader.com) •  
Website: [www.hctrainingleader.com](http://www.hctrainingleader.com)

# Expert Online Training for Your Healthcare Practice



## Telehealth Regulatory Considerations: Tips for Compliance

ANNE M. BRENDEL, ESQ.  
ASSOCIATE, HEALTHCARE & LIFE SCIENCES  
GOODWIN PROCTER, LLP




HEALTHCARE  
TRAINING  
LEADER  
Expert Medical Practice Solutions

Get more helpful tips and targeted training for your practice at:  
[www.hctrainingleader.com](http://www.hctrainingleader.com)  
Call us: 800-767-1181

1

**Disclaimer: This presentation and publication is provided with the understanding that it does not constitute the rendering of legal advice or other professional advice.**



HEALTHCARE  
TRAINING  
LEADER

[www.hctrainingleader.com](http://www.hctrainingleader.com)

2

# Agenda

- Telehealth Regulatory Issues
  - Licensure
  - Physician-Patient Relationship
  - Informed Consent
  - Patient Identification
  - E-Prescribing
  - Supervision
  - Medicare/Medicaid Coverage Limitations
  - Patient Privacy
- Corporate Practice of Medicine
- Telefraud & Compliance Considerations

HEALTHCARE  
TRAINING  
LEADER

www.hctrainingleader.com

3

# Telehealth Regulatory Issues

HEALTHCARE  
TRAINING  
LEADER

www.hctrainingleader.com

4

# Telemedicine and Professional Licensure Laws



- **Generally, a physician must be licensed in a particular state to practice in that state**
- e.g., “No person shall practice medicine in any of its departments within this state unless and until such person has obtained a license from the board created by § 63-6-101.” Tenn. Code Ann. § 63-6-201(1)

# Licensure



- Typical definition of “practice of medicine”
  - “Any person shall be regarded as practicing medicine, within the meaning of this chapter, who treats, or professes to diagnose, treat, operates on or prescribes for any physical ailment or any physical injury to or deformity of another.” Tenn. Code Ann. § 63-6-204(a)(1)
- Providers rendering services in a state where they are not properly licensed or authorized to provide medical services may be engaging in the unlicensed practice of medicine – and their counsel may be “aiding and abetting” such practice.
- Providers must be licensed in the state where the patient is located when clinical services are rendered, unless an “exception” applies.

## Interstate Practice of Medicine



- Exceptions to general licensure requirement:
  - Consultation Exception
  - Special or Temporary Telemedicine License
  - Licensure by Endorsement
  - Physician Interstate Medical Licensure Compact
  - **COVID-19 Waivers**

## Physician-Patient Relationship

- States have varying requirements for establishing a physician-patient relationship via telehealth
  - Synchronous versus asynchronous
  - Prohibition of online questionnaires
  - Specific clinical services
  - Standard of care never changes

## Informed Consent

- Again, state laws vary with regard to informed consent requirements
  - Some specifically explain what must be included in a telehealth informed consent
  - Others require only that the consent is written
  - Others permit verbal consent when documented in the patient's medical record
  - Other states laws are silent

## Patient Identification Verification

- States require verification of patient identification prior to providing services but provide little to no guidance as to appropriate methods for verifying patient identities
  - Options
    - Photo identification(e.g., driver license, passport)
      - Via store and forward or live video
    - Verification platform
    - Match patient insurance address to mailing address

## E-Prescribing: Federal Law



- DEA Registration
  - Special telehealth registration pending
- Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Pub. L. No. 110-425)
  - **Prohibits online pharmacies from dispensing controlled substances without a valid prescription from a physician who has examined the purchaser in person**

11

## E-Prescribing: State Law



- Other Prescription Drugs
  - A number of states require that a physician physically examine a patient before prescribing drugs for the patient
  - Every state prohibits "unprofessional conduct"
  - Numerous state medical boards prohibit prescribing based solely on an online questionnaire or consultation
  - Exceptions

12



## Supervision of Nurse Practitioners

- NP scope of practice varies by state
  - Prescriptive authority in most states
  - Some states may limit the types of drugs
- Collaboration Agreement or Written Protocols
  - Some states may have exceptions for experienced NPs
- Number of NPs a physician can supervise may be limited
  - New York limits to 4 NPs
  - California limits to 4 prescribing NPs
- Chart review may be required
  - Georgia requires review of 10% of charts quarterly
- Physician must be available for consultation and/or supervision
  - Georgia must provide onsite supervision quarterly



[www.hctrainingleader.com](http://www.hctrainingleader.com)

13

## Supervision of Physician's Assistants

- Physician Assistant (PA) scope of practice varies by state
- Written guidelines or protocols
- PAs have prescriptive authority, but types of drugs may vary
  - Pennsylvania permits prescribing Schedule II-V; Schedule II initial limited to 72 hours dose and 30-day requires MD's approval
- Number of PAs a physician can supervise may be limited
  - Pennsylvania limits to 4 PAs
- Periodic chart review or co-signature may be required
  - Tennessee requires review of at least 20% of all charts, 100% for specialty (every 30 days)
- Physician supervision requirements may vary
  - Tennessee requires supervising MD required to visit remote sites every 30 days



[www.hctrainingleader.com](http://www.hctrainingleader.com)

14

## Telemedicine: Medicare Coverage (Traditional Limitations)

- 5 conditions of coverage must be met to qualify for Medicare reimbursement of a telehealth service
  - Beneficiary must be at an originating site in a qualifying rural area (outside of Metropolitan Statistical Area or in a Health Professional Shortage Area in a rural census tract)
  - Originating site must be one of eight categories:
    - Physician Office, Hospital, Critical Access Hospital, Rural Health Clinic, FQHC, Hospital-based or CAH-based Renal Dialysis Center, SNF, Community Mental Health Center
  - Services are provided by one of ten types of eligible distant site practitioners
    - MD, NP, PA, Nurse-midwife, Clinical Nurse Specialist, Certified Registered Nurse Anesthetist, Clinical Psychologist, Clinical Social Worker, Registered Dietitian or Nutrition Professional
  - Communication via interactive audio and video telecommunications system that permits real-time communication
  - CPT/HCPCS code included in list of covered Medicare telehealth services

15

## Telemedicine: Medicare Coverage (COVID-19 Era)

- CMS Expanded Telehealth Coverage
  - 200+ telehealth services added to Medicare fee-schedule
  - Provider types expanded to include physical therapists, occupational therapists, speech language pathologists, and clinical psychologists
- CMS Reduces Barriers to Telehealth
  - Qualifying originating sites expanded to all locations
  - Technology requirements reduced (for both new and established patients)
    - Audio-only permitted
    - Store and forward technology permitted

16

## Telemedicine: Medicaid Coverage

- States have the option to determine whether (or not) to cover telemedicine, including:
  - What types of telemedicine to cover
  - Where in the state it can be covered
  - How it is provided and covered
  - What types of telemedicine may be provided by certain practitioners
  - How much to reimburse for telemedicine services, as long as such payments do not exceed federal limits
- 48 states and Washington, DC reimburse for some form of live video in Medicaid fee-for-service
- 15 states provide reimbursement for store-and-forward
- 6 states have some form of rural or geographic restriction

17

## Patient Privacy

- Telehealth involves the practice of medicine, so all applicable state and federal laws regarding patient medical record privacy and security still apply

18

# Corporate Practice of Medicine



[www.hctrainingleader.com](http://www.hctrainingleader.com)

19

# Corporate Practice of Medicine

- Restrictions on the “corporate practice of medicine” (“CPOM”) in many states prohibit corporations and other business entities from practicing medicine or employing a physician to practice medicine on the corporation’s behalf
- **A majority of states have some form of CPOM prohibition**, however the scope of such prohibitions vary by state
  - Most states have CPOM exceptions that allow physicians to practice medicine through partnerships, professional service corporations, and/or limited liability companies, but usually only if owned exclusively by physicians
- Corporate practice limitations frequently apply to other licensed professions, like dentistry



[www.hctrainingleader.com](http://www.hctrainingleader.com)

20

## Fee Splitting

- **Most states with CPOM laws also prohibit “fee splitting”** by physicians i.e., the sharing of a physician's professionally earned fees with non-physicians
  - **Example:** Fee for marketing services of 10% of professional fees for referred cases is illegal fee splitting. *E&B Marketing Enterprises, Inc. v. Ryan* (Ill. App. 1991)
  - **Example:** Payment of 20% of gross revenue from dental practice as partial consideration for the occupancy and use of a fully-equipped dental facility under a long-term lease violated public policy. *Sachs v. Saloshin* (N.Y. App. Div. 1988)
- As with CPOM, fee-splitting prohibitions vary from state to state
  - Some state laws tie the fee-splitting prohibition to referrals; others contain a blanket prohibition
  - Some states prohibit sharing fees with other physicians
  - Any agreement that provides for a payment based on a physician's revenues must be analyzed under state fee splitting rules
    - If Medicare or other federal healthcare program services are provided, a federal Anti-Kickback analysis is also warranted

21

## Friendly PC Model

- A “friendly PC” is an entity owned by licensed physicians and affiliated with a management services organization (MSO)
- The friendly PC is generally organized as a professional corporation, but may take any corporate form that is authorized by state law to engage in the practice of medicine (e.g., PLLC)
- Friendly PC contracts with MSO for management services
- Stock Transfer Agreement requires transfer of friendly PC shares to designee of MSO upon certain events such as termination of management services agreement

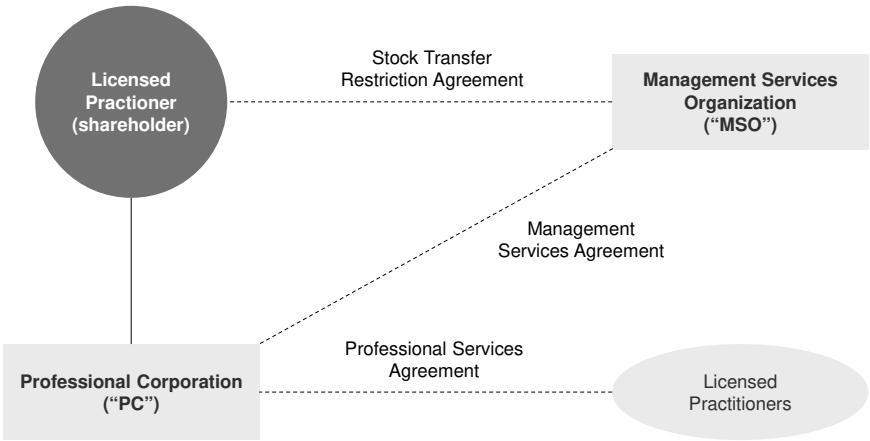
22

## Friendly PC Model (contd.)

- Limitations on MSO relationship with PC (in states that prohibit corporate practice)
  - **PC must maintain control of clinical matters**
  - Some CPOM states prohibit purchase of medical equipment or supplies by the MSO because these may be clinical decisions (e.g., North Carolina)
  - Control of PC by MSO generally prohibited
  - Compensation of MSO for services must be consistent with fair market value
    - Some states restrict compensation arrangements based on a percentage of PC revenue (e.g., New York), while other states permit such arrangements (California)
  - Specific limitations vary by state

23

## Friendly PC Model (contd.)



24

# Telefraud & Compliance Considerations



[www.hctrainingleader.com](http://www.hctrainingleader.com)

25

# Telehealth Fraud Enforcement

- Telehealth Becomes OIG’s Top Enforcement Priority
  - 2020 Nationwide Telefraud Takedown
    - OIG charged over 354 defendants
      - Telehealth companies, executives, practitioners, pharmacies, and laboratories
  - Uncovered alleged fraud schemes totaling more than \$6 billion
- Data Analytics
  - Statistical outliers invite government scrutiny
  - Efficient identification of potentially abusive patterns of ordering and billing
- More cases likely to follow
  - January 2021 Work Plan: Audits of Medicare Part B Telehealth Services During the COVID-19 Public Health Emergency
  - February 2021 Work Plan: Audits of Medicare Part B Laboratory Services During the COVID-19 Pandemic



[www.hctrainingleader.com](http://www.hctrainingleader.com)

26

## Compliance Check-Up

- Ensure compliance with state laws
  - Licensing
  - Prescribing
  - Ancillary provider supervision
  - Corporate practice of medicine
  - Fee-splitting restrictions
- Compliance Program
  - Create and implement a Compliance Program
  - Review and Update Compliance Program

## Compliance Check-Up

- OIG's 7 Essential Elements
  - Conduct internal monitoring and auditing.
  - Implement compliance and practice standards.
  - Designate a compliance officer or contact.
  - Conduct appropriate training and education.
  - Respond appropriately to detected offenses and develop corrective action.
  - Develop open lines of communication with employees.
  - Enforce disciplinary standards through well-publicized guidelines.



## What to do if the government contacts you?

- Types of Government Contact
  - Telephone call
  - On-Site audit
  - Subpoena
  - Civil Investigative Demand
  - Indictment
- Immediately speak with health care counsel experienced with enforcement actions
  - Minimize potential issues
  - Investigate potential liability
  - Evaluate potential reduction in liability

## Questions?



**ANNE M. BRENDDEL, ESQ.**

ASSOCIATE, HEALTHCARE & LIFE SCIENCES

GOODWIN PROCTER, LLP

[ABRENDEL@GOODWINLAW.COM](mailto:ABRENDEL@GOODWINLAW.COM)