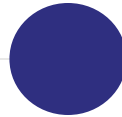


TELEPSYCHIATRY – MANAGING THE MAYHEM



**Donna Vanderpool, MBA, JD
Director of Risk Management
Professional Risk Management Services (PRMS)**

**NECCAP
December 5, 2020**

Top 10 Myths about Telepsychiatry

ICNS Online Editor | September 1, 2017 | 0 Comments



by Donna Vanderpool, JD

Ms. Vanderpool is Vice President, Risk Management, at PRMS, Inc.

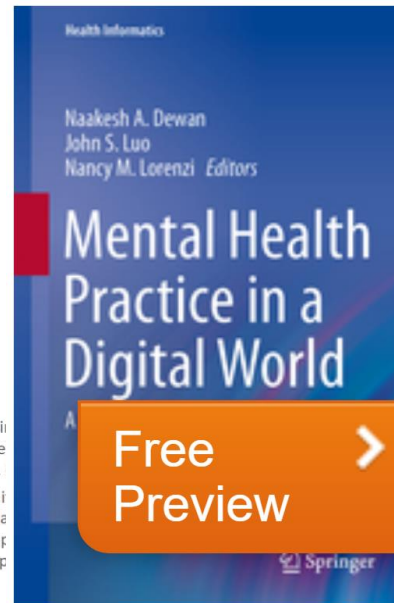
The technology for remote treatment is advancing rapidly. The regulatory environment which psychiatrists practice telepsychiatry is also evolving but at a much slower technology. As introduced in this Journal years ago by my colleague Charles D. article, "Telepsychiatry and Risk Management,"¹ there is still a lack of uniformity even whether—states address telemedicine requirements. This discrepancy has many myths around this topic. Fortunately, we are starting to see some concepts are generally consistent, regardless of the state, allowing us to clear up some of the misunderstandings about telepsychiatry.

MYTH #1

Services are deemed to be rendered where the psychiatrist is located.

Reality. All states are clear that a healthcare provider's services are rendered where the patient is physically located at the time of treatment. This fact has several implications, including the following:

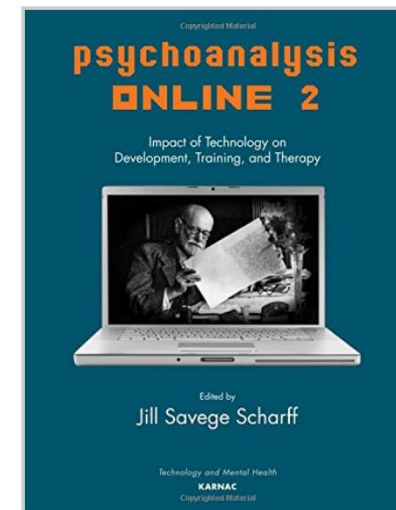
1. If the patient is in a different state than the provider, and the provider is not licensed in the patient's state, the patient's state licensing board should be contacted to determine whether licensure in the patient's state is required. While almost all states require some type of licensure or registration, the issue seems to be fact-specific (see Myth #2). Note that providers do not want to be found practicing without a license, as that could have criminal and medical malpractice insurance implications.
2. The provider will need to comply with all relevant laws not only in his or her own state (establishing a treatment relationship, prescribing requirements, duty to warn, etc.) but also in the patient's state.



Chapter 8 An Overview of Practicing High Quality Telepsychiatry

Donna Vanderpool

Abstract Providing psychiatric services remotely via telepsychiatry can be an effective care delivery model. Given the increasing need for psychiatric services, utilization of telepsychiatry is expected to increase for both consultation and treatment purposes. There are currently regulatory constraints, such as licensure, in-person examination, and prescribing requirements that pose significant barriers to the widespread adoption of telepsychiatry. However, these regulatory barriers are being evaluated by the states and are slowly being resolved. The steps to practicing quality telepsychiatry are: determine exactly what type of telepsychiatry you want to practice; determine how you want to practice and what technology will be used; address licensure requirements in the patient's state; address in-person examination and prescribing requirements in your state and the patient's state; address other



Ms. Vanderpool has no financial relationships with commercial interests to disclose

DISCLAIMERS

- Nothing presented here is legal advice
- There is little consistency in how states are addressing telemedicine
- Things can change daily
 - › Federal regulators are relaxing requirements
 - › State regulators are relaxing requirements, then undoing the relaxations
- What is true today may not be true tomorrow

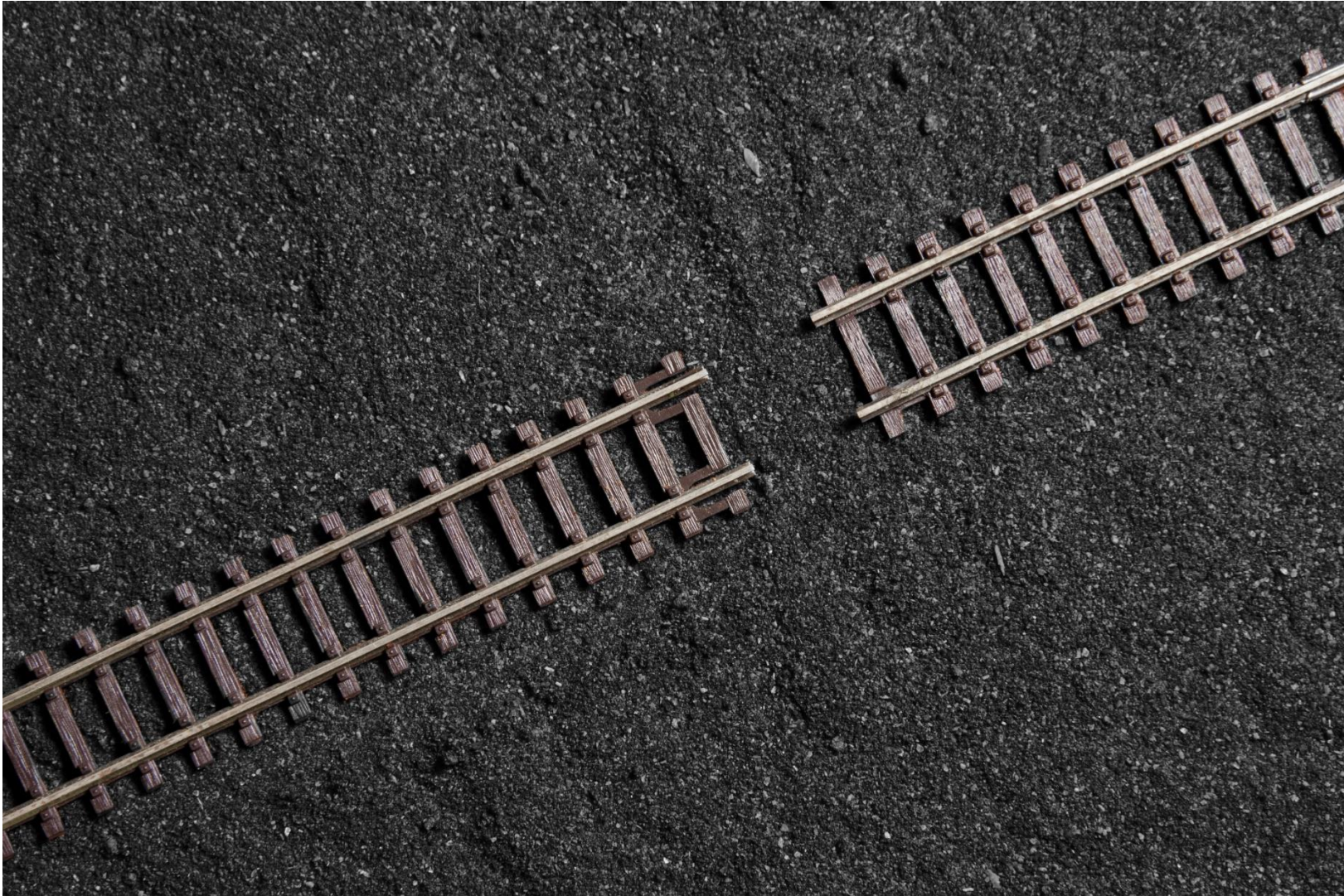
LEARNING OBJECTIVES

At the conclusion of this program, attendees will be able to:

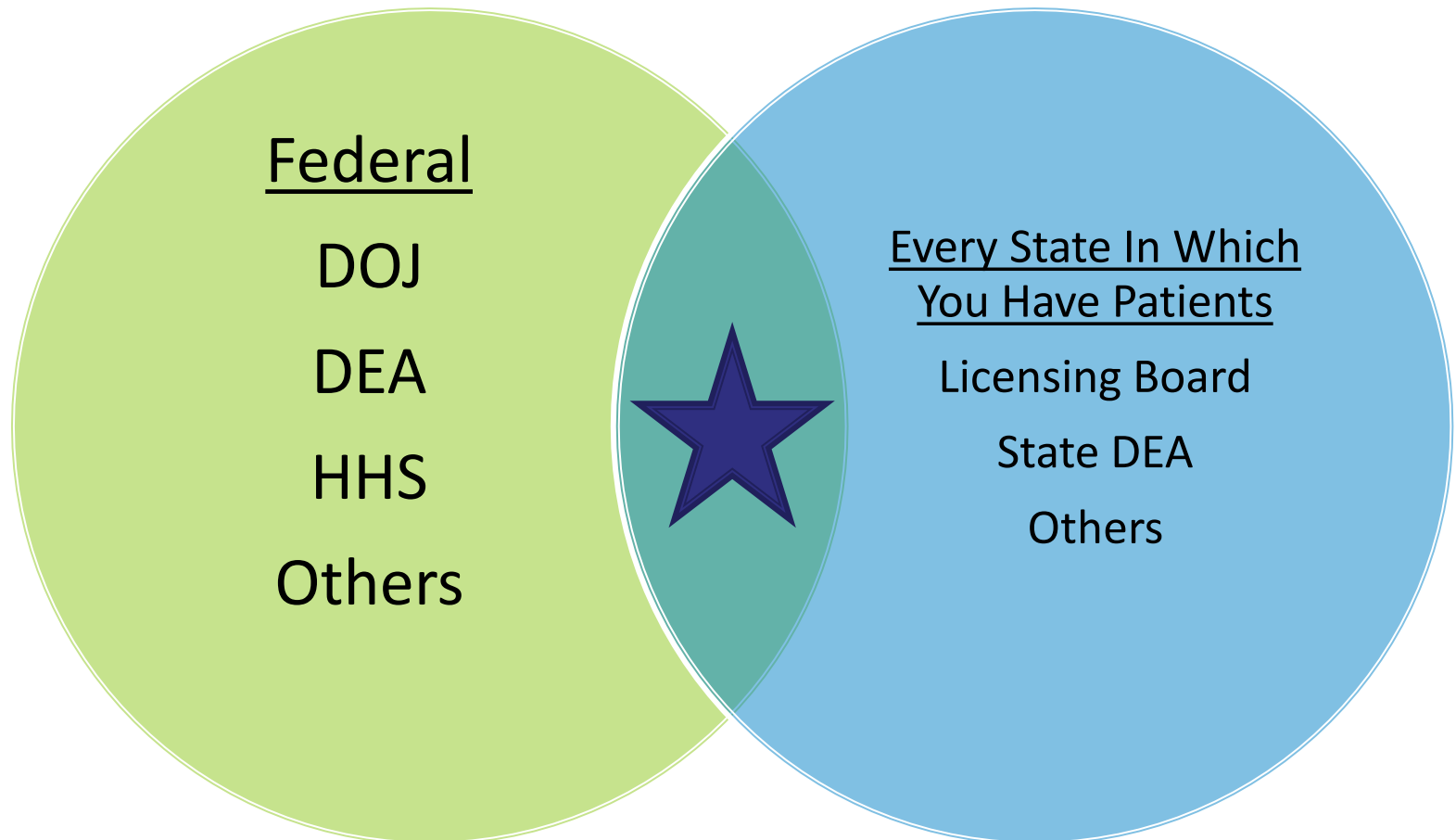
- Explain at least two modifications to the regulatory requirements for telepsychiatry, based on the pandemic
- Discuss how the pandemic affects the standard of care for the delivery of psychiatric services
- Understand the various possible implications when the federal government's Public Health Emergency expires

AGENDA

- Phase 1: Pre-pandemic
- Phase 2: Pandemic
- Phase 3: Post-pandemic
- Q & A



PHYSICIAN REGULATORS





INTERNET PRESCRIBING

- Internet prescribing based solely on online questionnaire
 - Consequence #1: State asserted jurisdiction over out-of-state physician for treatment rendered in the state
- *Hageseth* case (150 Cal.App.4th 1399):
 - CO MD pled no contest to **felony** charge of unlawful practice of medicine in CA; sentenced to nine months in jail
 - Civil case against MD was dropped

INTERNET PRESCRIBING

- Internet prescribing based solely on online questionnaire
 - › Consequence #2: Regulators want to prevent this
 - Such as by requiring in-person visit prior to prescribing
 - › Two regulatory prohibitions:
 - For providers: States regulate prescribers – and prohibit prescribing based solely on an online questionnaire
 - Pharmacies: Online pharmacies cannot fill prescriptions based solely on an online questionnaire
 - › Ryan Haight Act – amends Controlled Substances Act



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FOR IMMEDIATE RELEASE

Contact: Garrison Courtney

Number: 202-307-7977

April 13, 2009

New Rules Governing Internet Pharmacies Go Into Effect Next Week *Regulations Implement Ryan Haight Act*

APR 13 -- (Washington, DC)- New Drug Enforcement Administration (DEA) regulations implementing the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 go into effect Monday, April 13. These regulations will help to prevent the illegal diversion of powerful controlled substances by means of the Internet. Such medications can cause harm to consumers for whom they were not intended. The Interim Final Rule was published in the *Federal Register* this week, and the public has 60 days from its publication date to submit comments to the DEA.

The Ryan Haight Act, named for an 18-year-old who died after overdosing on a prescription painkiller he obtained on the Internet from a medical doctor he never saw, was enacted on October 15, 2008 through the joint efforts of his mother, Francine Haight, and members of Congress, with the support of the DEA.

"Now that this law has been put into force it will be harder for cyber-criminals to ply controlled substances over the Internet and easier for us to prosecute them," said DEA Acting Administrator Michele M. Leonhart. "These regulations add important new provisions to prevent the illegal distribution of controlled substances through the Internet. Its implementation will increase Internet safety and help prevent tragedies like Ryan Haight's death from happening again."

The statute amends the Controlled Substances Act (CSA) by adding several new provisions to prevent the illegal distribution of controlled substances by means of the Internet, including:

- New definitions, such as "online pharmacy" and "deliver, distribute, or dispense by means of the Internet";
- A requirement of at least one face-to-face patient medical evaluation prior to issuance of a controlled substance prescription;
- Registration requirements for online pharmacies;
- Internet pharmacy website disclosure information requirements; and
- Prescription reporting requirements for online pharmacies.

Consistent with the CSA itself, the Ryan Haight Act relates solely to controlled substances

FEDERAL REGULATION OF INTERNET PRESCRIBING

- Controlled Substance Act
 - › 21 USC § 829(e) – Controlled Substances Dispensed By Means of the Internet
 - “No controlled substance that is a prescription drug...may be delivered, distributed or dispensed by means of the Internet without a valid prescription.”
 - **“Valid prescription means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by –**
 - › **A practitioner who has conducted at least 1 in-person medical evaluation of the patient, or a covering practitioner**
 - › **In-person medical evaluation means a medical evaluation that is conducted with the patient in the physical presence of the practitioner”**

INTERNET PRESCRIBING

- Internet prescribing based solely on online questionnaire
 - › DEA seems to equate this with today's telemedicine

SIGNIFICANT CONSEQUENCES

The case of Dr. G:

- Issued prescriptions, including for controlled substances for patients in at least 9 states
 - › MD only licensed in NY and NJ
- DEA
 - › Suspended DEA registration for one year
- NY Board
 - › Suspended medical license for two years
 - › Fined \$12,000
 - › Restricted from prescribing controlled substances for 42 months
- NJ Board
 - › Suspended medical license for two years
 - › \$5,000 penalty + \$6,500 investigation costs



To: Donna Vanderpool, VP-Risk Management, PRMS

From: Matthew Lee, Bill Hake, Vince D'Angelo, Mary Jean Geroulo, Sabrina M. Ly, and Kristin Invanco

Date: April 12, 2016

Subject: Drug Enforcement Agency Registration in each State

File No.: 01592.00091

With the ever increasing proliferation of multiple state healthcare practices, providers must be aware of the need for separate DEA licenses in each state in which they practice.

CIVIL PENALTIES

In *U.S. v. Butterbaugh*, the government sued Dr. Barton Butterbaugh ("Butterbaugh") for prescribing controlled substances without a Drug Enforcement Administration ("DEA") registration in Washington State.¹ Butterbaugh was both an Arizona licensed physician and DEA registrant.² Through his employment with a Florida based company, eClinicMD, Butterbaugh volunteered to temporarily service patients in Washington after its Washington provider relocated to California.³ Between October 2010 and November 2012, Butterbaugh treated and prescribed medications to approximately 80 individuals in Washington.⁴ Prior to treating patients in Washington, Butterbaugh applied for and received a Washington medical license.⁵ However, he did not register with the DEA to dispense, administer, or distribute controlled substances in the state of Washington. During the 2 year period, Butterbaugh wrote over 1300 prescriptions for controlled substances for over 200 people.⁶

TELEPSYCHIATRY

- Providing psychiatric services remotely, typically through videoconferencing
 - Psychiatrist and patient are in different locations
- We are NOT talking about a patient on short vacation who needs prescription called in

TELEPSYCHIATRY

- Telephone treatment may or may not be considered telemedicine
 - Don't be confused by state Medicaid laws:
 - Typically say state won't reimburse for phone calls
 - Compliance with all state laws, including licensure laws, is still required

EVEN IF NOT TECHNICALLY TELEMEDICINE...

- You still need to meet the standard of care
- If patient is in a different state, you may still need a license in the patient's state

HIPAA REQUIREMENTS

- Privacy Rule
 - › Business Associate Agreement if has access to PHI
 - Check Privacy Policy
- Breach Notification Rule
 - › BA must notify covered entity of any breach
- Security Rule
 - › Encryption
 - › BA must provide audit trails – who has accessed PHI
 - › Include telepsych activities in Security Risk Assessments

TECHNOLOGY REQUIREMENTS

Example: NY OMH Requirements

“Technical Guidelines Checklist for Local Providers”

- Videoconferencing Applications
- Security and Protection of Data Transmission and Information
- Transmission Speed and Bandwidth
- Encryption
- Equipment

WHAT IS CLEAR – WHERE SERVICES ARE RENDERED

Treatment is rendered where the **patient** is physically located.

WHERE ARE TELEMEDICINE SERVICES RENDERED?

From the boards:

- NY: “It is the location of the patient that defines where the care has been delivered and the jurisdiction of applicable regulations”
- SC: “The Board adheres to the view that the practice of medicine occurs where the patient is physically located”

WHAT IS CLEAR – STANDARD OF CARE

Utilizing telemedicine does not alter the standard of care to which the physician will be held – it is the same standard of care that would apply if the patient was in the physician's office or facility.

TELEMEDICINE - STANDARD OF CARE

From WA MQAC *Appropriate Use of Telemedicine*:

“Practitioners using Telemedicine will be held to the same standard of care as practitioners engaging in more traditional in-person care delivery, including the requirement to meet all technical, clinical, confidentiality and ethical standards required by law.”

<https://www.doh.wa.gov/Portals/1/Documents/2300/2016/TelepsychologyGuidelines.pdf>

FACTORS THAT MAY EVIDENCE THE STANDARD OF CARE

- Statutes – federal and state
- Regulations – federal and state
- Court opinions – federal and state
- Other regulatory materials – federal and state (such as state medical boards)
- Authoritative clinical guidelines
- Policies and guidelines from professional organizations
- Journal / research articles
- Accreditation standards
- Facility policies and procedures

FROM MARYLAND

Regulation 10.32.05.06 Standard of Quality Care -

...

D. A physician practicing telemedicine shall:

- (1) Except when providing interpretive services, obtain and document patient consent;
- (2) Create and maintain adequate medical records
- (3) Follow requirements of Maryland and federal law and regulations with respect to confidentiality of medical records and disclosure of medical records...

HARRIS CASE

- Facts:
 - Psychiatrist did one-time consult via telemedicine
 - Made medication recommendations
 - Suicide 10 months later
 - Consulting psychiatrist sued
- Trial Court:
 - Granted psychiatrist's motion for summary judgment
- Appellate Court:
 - Reversed

FROM NORTH CAROLINA

Medical Board Position Statement – *Availability of Licensees to their Patients*

It is the position of the North Carolina Medical Board that once a relationship between a licensee and a patient is created, it is the duty of the licensee to provide care whenever it is needed or to assure that proper backup by a healthcare provider is available to take care of the patient during or outside normal office hours.

If the licensee is not going to be available after hours, the licensee must provide clear instructions to the patient for securing after-hours care. It is the responsibility of the licensee to ensure that the patient has sufficient information regarding how to secure after-hours care.

It should be noted that these duties are applicable to a licensee whether the licensee is practicing telemedicine or practicing medical through traditional means.

**Best Practices in Videoconferencing-Based Telemental Health
(April 2018)**



The American Psychiatric Association

and



The American Telemedicine Association



PRACTICE GUIDELINES FOR TELEMENTAL HEALTH WITH CHILDREN AND ADOLESCENTS

MARCH 2017

<https://www.cdphp.com/-/media/files/providers/behavioral-health/hedis-toolkit-and-bh-guidelines/practice-guidelines-telemental-health.pdf?la=en>

Resource Document on Telepsychiatry and Related Technologies in Clinical Psychiatry

APA Council on Psychiatry & Law

Special Acknowledgment

Patricia Recupero, M.D., J.D.
Carl Erik Fisher, M.D.

Approved by the Joint Reference Committee
January 2014

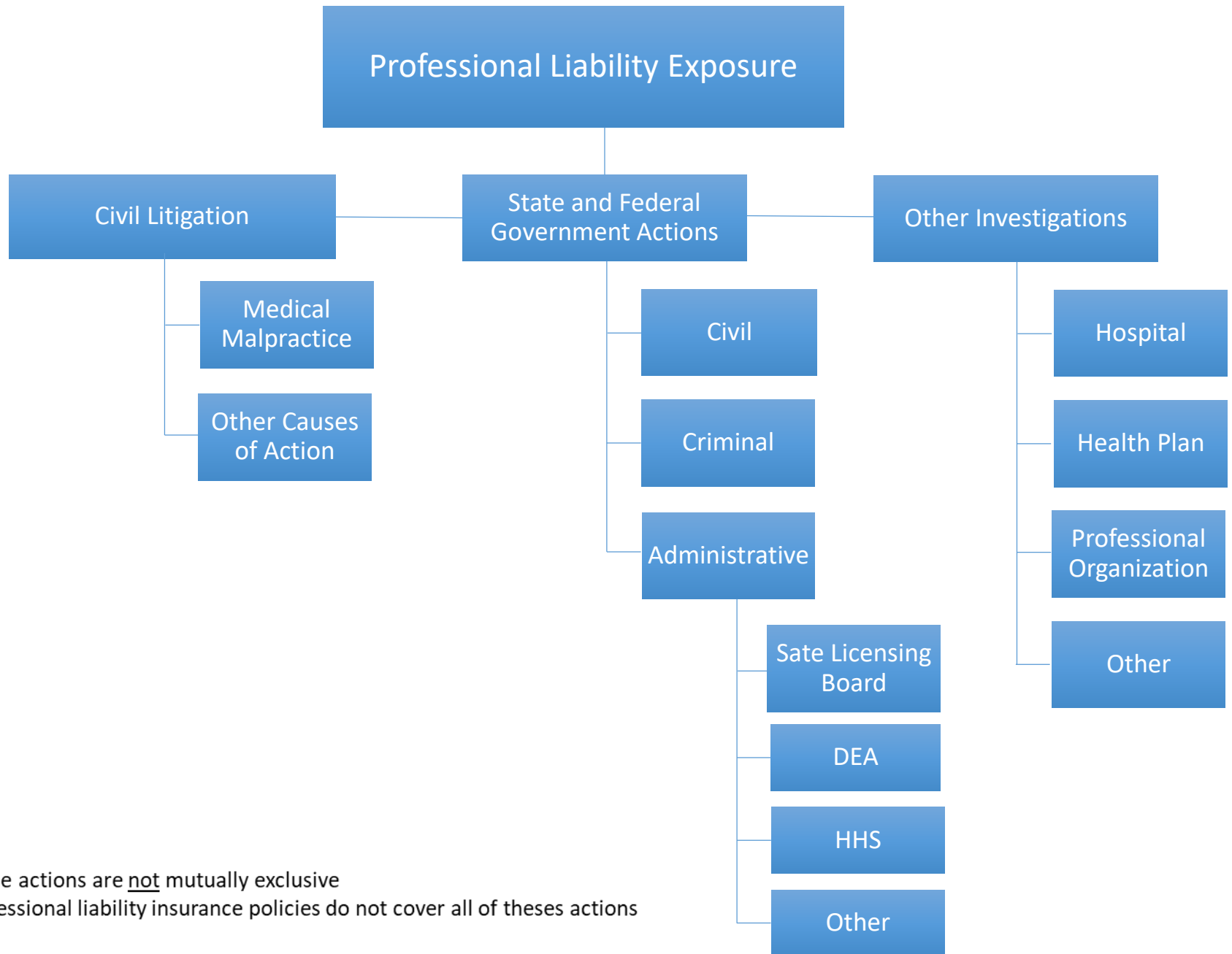
The findings, opinions, and conclusions of this report do not necessarily represent the views of the officers, trustees, or all members of the American Psychiatric Association. Views expressed are those of the authors." APA Operations Manual.

Abstract

The goal of this resource document is to address the major areas of the use of the Internet in communication with patients and the public in the practice of psychiatry. The rate of change of technological capabilities and their implementation is so rapid that the workgroup believes that it would be inappropriate to promulgate fixed rules for constantly changing situations. Rather, we seek to provide some questions to be considered when implementing any

new communication technology with patients or the public. This document seeks to address professional use of the Internet and does not discuss issues related to psychiatrists' use of social media and social networking sites such as Facebook or Twitter. In order to assist the practitioner, references to resource materials will be given. However, the reference is not an endorsement by either the APA or the members of the work group of the material contained therein.

As with the addition of any relatively new technology, there are complicated legal and ethical issues to consider, and it is beyond the scope of this resource document to provide an exhaustive list of the relevant concerns. This document aims, instead, to provide a general introduction to the use of the Internet in clinical psychiatry, to identify some of the key issues arising from the debate, and to provide some starting-point resources for physicians and other practitioners who may be interested in learning more about this developing area in health services. We expect that the prudent practitioner will use this document as a starting point only and that a more thorough investigation or research effort will be conducted before acting. The role of the Internet in medicine is an unsettled area of the law. There are few specific appellate court rulings on these issues. Often, reasoning from analogy is applied. The legal implications suggested herein may not be applicable in any or all jurisdictions. This resource document is not intended to be construed as a clinical practice guideline, nor to define a standard of care.



Notes:

- * These actions are not mutually exclusive
- * Professional liability insurance policies do not cover all of these actions

WHAT IS NOT CLEAR – STATE LICENSURE REQUIREMENTS

- Varies by state
 - › Full license
 - › Special purpose / telemedicine license
 - › Just registration
- Can be exceptions

TYPICAL TOPICS ADDRESSED IN TELEMEDICINE LAWS

- Informed consent
- Medical records
- Confidentiality and security
- Physician-patient relationship
- Follow-up care
- Verification of patient's identity
- Etc.

WHAT IS NOT CLEAR – IN-PERSON EXAMINATION

- Federal law (Ryan Haight Act)
- State law - no uniformity
 - ☐ Some boards do not address it
 - ☐ Some boards say in-person exam is not required
 - ☐ Some boards say it depends
 - On where the patient is located
 - On prescribing

NEW JERSEY STAT. 45:1-62:

USE OF TELEMEDICINE AND TELEHEALTH BY HEALTH CARE PROVIDERS; REQUIREMENTS

e. The prescription of Schedule II controlled dangerous substances through the use of telemedicine or telehealth shall be authorized only after an initial in-person examination of the patient, as provided by regulation, **and a subsequent in-person visit with the patient shall be required every three months for the duration of time that the patient is being prescribed the Schedule II controlled dangerous substance.**

However, the provisions of this subsection shall not apply, and the in-person examination or review of a patient shall not be required, when a health care provider is prescribing a stimulant which is a Schedule II controlled dangerous substance for use by a minor patient under the age of 18, provided that the health care provider is using interactive, real-time, two-way audio and video technologies when treating the patient and the health care provider has first obtained written consent for the waiver of these in-person examination requirements from the minor patient's parent or guardian.

WHAT IS NOT CLEAR – PRESCRIBING CONTROLLED SUBSTANCES

- State law varies
- Federal law is not understood

Compliance with State Prescribing Law

**Is prescribing controlled substances via telemedicine
allowed by prescriber's state and patient's state (if
different)?**

PRESCRIBING CONTROLLED SUBSTANCES VIA TELEMEDICINE

- No uniformity
 - › Some boards do not address it
 - › Some boards say yes
 - › Some boards say no
 - › Some boards say no, then yes in some cases!

**If prescribing controlled substances via telemedicine
allowed by prescriber's state and patient's state (if
different), under what conditions?**



www.nascsa.org/stateprofiles.htm



Events



Let's Get Social!



Get in touch!

Compliance with Federal Controlled Substances Act



To: Donna Vanderpool, VP-Risk Management, PRMS

From: Matthew Lee, Bill Hake, Vince D'Angelo, Mary Jean Geroulo, Sabrina M. Ly, and Kristin Invanco

Date: April 12, 2016

Subject: Drug Enforcement Agency Registration in each State

File No.: 01592.00091

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FEDERAL REGULATION

- Controlled Substances Act
 - › Amended in 2008 by the Ryan Haight Online Pharmacy Protection Act - 21 USC § 829(e)(3)

FEDERAL REGULATION

- Controlled Substances Act (as amended by the Ryan Haight Act)
 - “No controlled substance that is a prescription drug...may be delivered, distributed or dispensed by means of the Internet without a valid prescription.”
 - › Note: “dispense” is defined in §802(10) to include prescribing

FEDERAL REGULATION

- Controlled Substances Act (as amended by the Ryan Haight Act)
 - “Valid prescription means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by –
 - › A practitioner who has conducted **at least 1 in-person medical evaluation of the patient**, or a covering practitioner
 - In-person medical evaluation means a medical evaluation that is conducted with the patient in the physical presence of the practitioner

FEDERAL REGULATION

- Controlled Substances Act (as amended by the Ryan Haight Act)
 - Exception to the in-person visit requirement is “telemedicine”
 - › ***But as defined by the CSA***

FEDERAL REGULATION

- Controlled Substances Act (as amended by the Ryan Haight Act)
 - 7 definitions of telemedicine / 7 exceptions to in-person visit
 1. Patient in facility with federal DEA registration
 2. Patient in presence of a treater with DEA registration in patient's state
 3. Indian Health Service
 4. Public health emergency
 5. Special registration from Attorney General

FEDERAL REGULATION

- Controlled Substances Act (as amended by the Ryan Haight Act)
 - 7 definitions of telemedicine / 7 exceptions to in-person visit
 6. Medical emergency
 7. Other circumstances, as deemed by Attorney General and Secretary

NOT A LOW-RISK TELEPSYCHIATRY MODEL

- **1986:** MD licensed in NC
- **3-14-2007:** Secure Telemedicine sent e-mail searching for MDs to provide telemedicine services
 - › Included opinion letter from attorney appearing to say that telephone patient evaluation and subsequent prescribing is allowed
- **3-20-07:** MD signed contract; subsequently became licensed in 12 other states
- **5-07:** Over 3 days, MD issued a limited number of prescriptions after telephone conferences with patients; many prescription requests denied
- **5-08:** NC Medical Board charged MD with unprofessional conduct – prescribing medications to patients without a physical examination and in the absence of a prior physician-patient relationship
 - › **7-08:** MD entered into Consent Order; license suspended for 30 days, stayed with probation

NOT A LOW-RISK TELEPSYCHIATRY MODEL

(continued)

- 2-09: VT Medical Board – public reprimand
- 5-09: NV Medical Board – reprimand
- 7-09: CA Medical Board – license surrender
- 7-09: TN Medical Board – probation
- 10-09: DC Medical Board – fine + public reprimand
- 3-10: MD filed suit against Secure Telemedicine

Zaslow v. Secure Telemedicine, LLC (2010 WL 1024224)

NORTH CAROLINA MEDICAL BOARD CONSENT ORDER

Included, among other issues, the finding of MD's unprofessional conduct by:

1. Assisting in the unauthorized practice of medicine by Secure Telemedicine
2. Splitting with Secure Telemedicine the fees he generated from practicing medicine



50-state survey: Establishment of a patient-physician relationship via telemedicine

The following compilation of state laws may be useful to state and national specialty medical societies in advocacy related to efforts to telemedicine laws or regulations that define establishment of a patient-physician relationship for purposes of treatment telemedicine.

All states allow a physician to establish a relationship with a new patient via telemedicine, though state laws differ. A few states include some caveats to that general rule, restricting the setting in which a patient must be located in order to establish the patient-physician relationship (e.g. limiting to established medical site), or the modalities that can be used to establish such a relationship (e.g. telephone versus two-way audio and video technology). More details on each state's laws and regulations are below.

The AMA believes that a valid patient-physician relationship must be established before the provision of telemedicine services, through: (i) A face-to-face examination, if a face-to-face encounter would otherwise be required in the provision of the same service not delivered via telemedicine; or (ii) A consultation with another physician who has an ongoing patient-physician relationship with the patient. The physician who has established a valid physician-patient relationship must agree to supervise the patient's care; or (iii) Meeting standards of establishing a patient-physician relationship included as part of evidence-based clinical practice guidelines on telemedicine developed by major medical specialty societies, such as those of radiology and pathology. Exceptions include on-call, cross coverage situations; emergency medical treatment; and other exceptions that become recognized as meeting or improving the standard of care. If a medical home does not exist, telemedicine providers should facilitate the identification of medical homes and treating physicians where in-person services can be delivered in coordination with the telemedicine services. (Policy H-480.948, Coverage of and Payment for Telemedicine.)

| State | Statute | Establish relationship via telemedicine? | Notes |
|---------|----------------------------------|--|---|
| Alabama | AAC 540-X-15-.09 | Only at established medical site (& other exceptions including mental | Separate rules for telemedicine provided at a medical site vs non-medical site. Telehealth Medical Services Provided at an Established Medical Site <ul style="list-style-type: none">Telehealth medical services provided at an established medical site may be used for all patient visits, including initial evaluations to establish a provider-patient relationship. |

TELEMENTAL / TELEBEHAVIORAL SURVEY



Associated Practices

[Behavioral Health](#)

[Digital Health](#)

[Telehealth & Telemedicine](#)

[Telemental/Telebehavioral Health](#)

50-State Survey on Telemental Health Laws in the United States

Epstein Becker Green is pleased to present the [50-State Survey of Telemental/Telebehavioral Health \(2016\)](#), a groundbreaking, comprehensive survey on the laws, regulations, and regulatory policies impacting telemental health in all 50 states and the District of Columbia.

While other telehealth studies exist, this survey is focused solely on the remote delivery of *behavioral* health care.

Compiled by attorneys in Epstein Becker Green's [Telehealth & Telemedicine practice](#), the survey details the rapid growth of telemental health—mental health care delivered via interactive audio or video, computer programs, or mobile applications—and the increasingly complex legal issues associated with this trend. Additionally, the survey provides one source for state-by-state coverage of legal issues related to telemental health, such as:

- › Definitions of “telehealth” or “telemedicine”
- › Licensure requirements
- › Governing bodies
- › Reimbursement and coverage issues
- › The establishment of the provider-patient relationship
- › Provider prescribing authority
- › Accepted modalities for delivery (e.g., telephone, video) to meet standards of care



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STATE TELEMEDICINE GAPS REPORTS

<https://www.americantelemed.org/?s=gaps+report>




Telehealth Policy

National Policy

State Laws and Reimbursement
Policies

Medicare

Medicaid

Legal Barriers

Health Information Technology

HIPAA

The Federal Trade Commission and
Professional Licensure Boards

California Policy

Medi-Cal

Telehealth Advancement Act

Home » Telehealth Policy » National Policy » State Laws and Reimbursement Policies » Arizona

Arizona

Use these filters to view specific areas or types of law. Use the "status" filter to view pending law.

Area of Law

Broadband
Demonstrations & Pilot Projects
Network Adequacy
Professional Board Regulation
Provider-Patient Relationship/In-Person Exam
Telemedicine/Telehealth Definition
Live Video Reimbursement
Store and Forward Reimbursement

Law Type

- Any -

Status

Current

Apply

TELEMEDICINE/TELEHEALTH DEFINITION

LAW

Under Arizona Statute, Public Health & Safety,
"telemedicine means the practice of health care
delivery, diagnosis, consultation and treatment

REGULATION

Under State Administrative Code, Department of
Insurance, Health Care Services Organizations
Oversight "telemedicine means diagnostic

MEDICAID PROGRAM

Service delivery via telemedicine can be in one of
two models: Real time means the interactive, two-
way transfer of information and medical data



Telemedicine Policies

Board by Board Overview

Document Summary:

- Forty-eight (48) state boards, plus the medical boards of District of Columbia, Puerto Rico, and the Virgin Islands, require that physicians engaging in telemedicine are licensed in the state in which the patient is located.
- Fifteen (15) state boards issue a special purpose license, telemedicine license or certificate, or license to practice medicine across state lines to allow for the practice of telemedicine.
- Four (4) state boards require physicians to register if they wish to practice across state lines.
- Twenty-eight (28) states, plus the District of Columbia, require both private insurance companies and Medicaid to cover telemedicine services to the same extent as face-to-face consultations.
- Eighteen (18) states currently require only Medicaid to cover telemedicine services.
- One (1) state requires only private insurance companies to reimburse for services provided through telemedicine.

| | State License | Reimbursement Parity | Other Rules/Regulations (citation only) |
|--|---------------|----------------------|---|
|--|---------------|----------------------|---|



FOR IMMEDIATE RELEASE

Contact: Drew Carlson, (817)868-4043;

dcarlson@fsmb.org

State Medical Boards Adopt Policy Guidelines for Safe Practice of Telemedicine

Denver, Colorado (April 26, 2014) – Representatives of state medical licensing boards today approved updated guidelines to help ensure the safety and quality of medicine when it is practiced using telemedicine technology – which can connect a patient in one location with care provider in another location.

The *Model Policy on the Appropriate Use of Telemedicine Technologies in the Practice of Medicine*, adopted by the Federation of State Medical Boards (FSMB), provides much-needed guidance and a basic roadmap that state boards can use to ensure that patients are protected from harm in a fast-changing health-care delivery environment.

Among its key provisions, the model policy states that the same standards of care that have historically protected patients during in-person medical encounters must apply to medical delivered electronically. Care providers using telemedicine must establish a credible "patient-physician relationship," ensuring that patients are properly evaluated and treated and that providers adhere to well-established principles guiding privacy and security of personal health information, informed consent, safe prescribing and other key areas of medical practice.

"Telemedicine offers wonderful tools to help expand treatment options for patients – particularly in helping provide care in remote areas, lowering costs and helping support preventive care efforts," said FSMB President and CEO Humayun J. Chaudhry, DO, MACP. "As telemedicine has grown, so too, has the need for clear, common-sense guidelines that help health care providers transition to this exciting new environment in a safe way."

Dr. Chaudhry noted that the new guidelines are designed to provide flexibility in the use of technology by physicians – ranging from telephone and email interactions to videoconferencing – as long as they adhere to widely recognized standards of patient care.

Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine

*Report of the State Medical Boards' Appropriate Regulation of Telemedicine (SMART)
Workgroup*

Introduction

The Federation of State Medical Boards (FSMB) Chair, Jon V. Thomas, MD, MBA, appointed the State Medical Boards' Appropriate Regulation of Telemedicine (SMART) Workgroup to review the "Model Guidelines for the Appropriate Use of the Internet in Medical Practice" (HOD 2002)¹ and other existing FSMB policies on telemedicine and to offer recommendations to state medical and osteopathic boards (hereinafter referred to as "medical boards" and/or "boards") based on a thorough review of recent advances in technology and the appropriate balance between enabling access to care while ensuring patient safety. The Workgroup was charged with guiding the development of model guidelines for use by state medical boards in evaluating the appropriateness of care as related to the use of telemedicine, or the practice of medicine using electronic communication, information technology or other means, between a physician in one location and a patient in another location with or without an intervening health care provider.

This new policy document provides guidance to state medical boards for regulating the use of telemedicine technologies in the practice of medicine and educates licensees as to the appropriate standards of care in the delivery of medical services directly to patients² via telemedicine technologies. It is the intent of the SMART Workgroup to offer a model policy for use by state medical boards in order to remove regulatory barriers to widespread appropriate adoption of telemedicine technologies for delivering care while ensuring the public health and safety.

In developing the guidelines that follow, the Workgroup conducted a comprehensive review of telemedicine technologies currently in use and proposed/recommended standards of care, as well as identified and considered existing standards of care applicable to telemedicine developed and implemented by several state medical boards.

Model Guidelines for State Medical Boards' Appropriate Regulation of Telemedicine

Section One. Preamble

The advancements and continued development of medical and communications technology have had a profound impact on the practice of medicine and offer opportunities for improving the delivery and accessibility of health care, particularly in the area of telemedicine, which is the practice of medicine using electronic communication, information technology or other means of

¹ The policy on the Appropriate Use of Telemedicine Technologies in the Practice of Medicine supersedes the Model Guidelines for the Appropriate Use of the Internet in Medical Practice (HOD 2002).

² The policy does not apply to the use of telemedicine when solely providing consulting services to another physician who maintains the physician-patient relationship with the patient, the subject of the consultation.



Learning Center

Missed the conference? The ATA 2016 recordings are available for purchase! Packages include access to full, high-definition audio, synced with the presenter's PowerPoint slides.



Welcome to the ATA Learning Center, your "go to" telehealth resource

Learn and stay current in this rapidly evolving field and take advantage of key educational content by telehealth experts. The Learning Center provides you with learning tools in a variety of convenient formats including on-demand courses, webinars, and recorded conference sessions.

Courses/ Toolkits

Resource Toolkits and On-Demand Courses

ATA's self-paced on-demand courses and resource toolkits offer the best in telehealth information and innovation all from the comfort of your own home.

WEBINARS

Webinars

ATA's webinars bring together the telehealth industry leaders across the country to help pave the way for the telehealth transformation of healthcare.

RECORDINGS

Conference Recordings

ATA's conference recordings have any session or course that you may have missed at our conferences. Here you can browse to find the cutting edge information on the telehealth industry.

TAKE AWAY POINT

Contact all applicable medical boards
to determine if you can do what you want to do
without violating applicable laws!

- Licensure requirements?
- In-person physical examination required?
- ?

LEGAL / ADMINISTRATIVE HURDLES

- State licensure needed?
- Complying with both states' laws
- Standard of care – same as in physical presence
- Prescribing controlled substances
 - › Ryan Haight Act
 - › DEA registrations
- Privacy and security issues
- Billing issues
- Confirm professional liability insurance policy coverage of telemedicine – any restrictions?

MEDICAL MALPRACTICE INSURANCE

- Not all carriers cover telemedicine
- Some carriers will only cover telemedicine if specific conditions are met
 - › Ex: only cover if patient is in physician's state
 - › Ex: only consultation, not treatment
 - › Ex: only cover in desirable jurisdictions
- Not all carriers will cover services rendered out of state
 - › May not be set up to defend in patient's state
- Some carriers may have premium surcharge for telemedicine
 - › Ex: if patients are in a state without damage caps



Telehealth Professional Liability Insurance

Providing Telehealth Services across State Lines

Providers who practice telehealth across State lines may experience barriers with liability coverage. Carriers who are licensed to provide liability coverage in a limited number of states are not able to cover telehealth services rendered in a state in which they are not licensed.³



³ In Maryland, Medical Mutual, the top liability insurance provider, is only licensed to cover physicians practicing in Maryland, the District of Columbia, or Virginia, and can only cover telehealth if the patient and the provider are located in one of those three locations.

Maryland Health Care Commission, March 2018

mhcc.maryland.gov

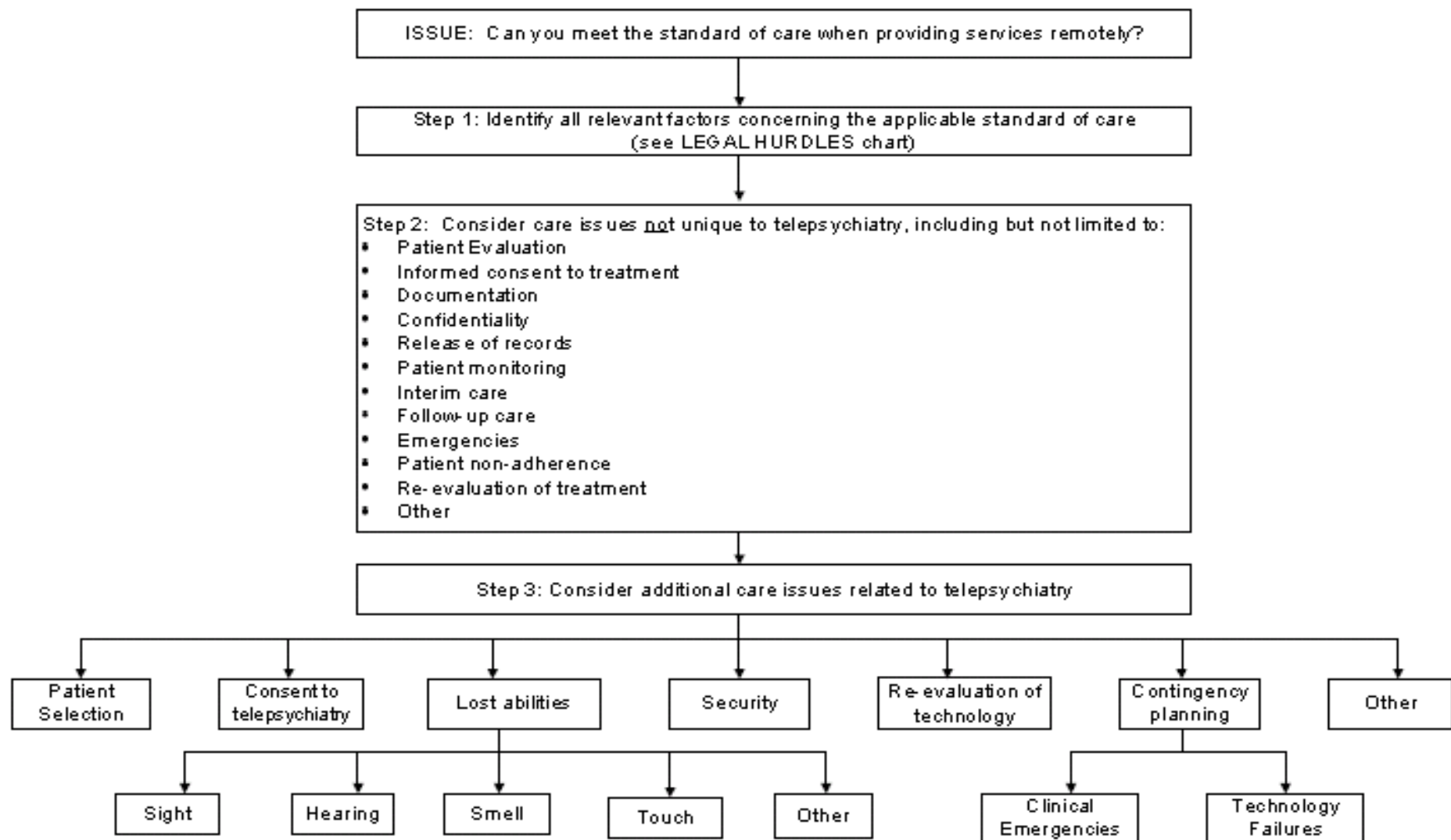
Accessed June 12, 2020

MEDICAL MALPRACTICE INSURANCE

- ASK:
 - › Does carrier cover telemedicine?
 - › Are there any restrictions?
 - › Are there any requirements?
 - › Is there a surcharge?
 - › Is there coverage for suits brought out of state?
- Resource: Telehealth Resource Centers - *Medical Malpractice and Liability*

TELEPSYCHIATRY

CLINICAL HURDLES



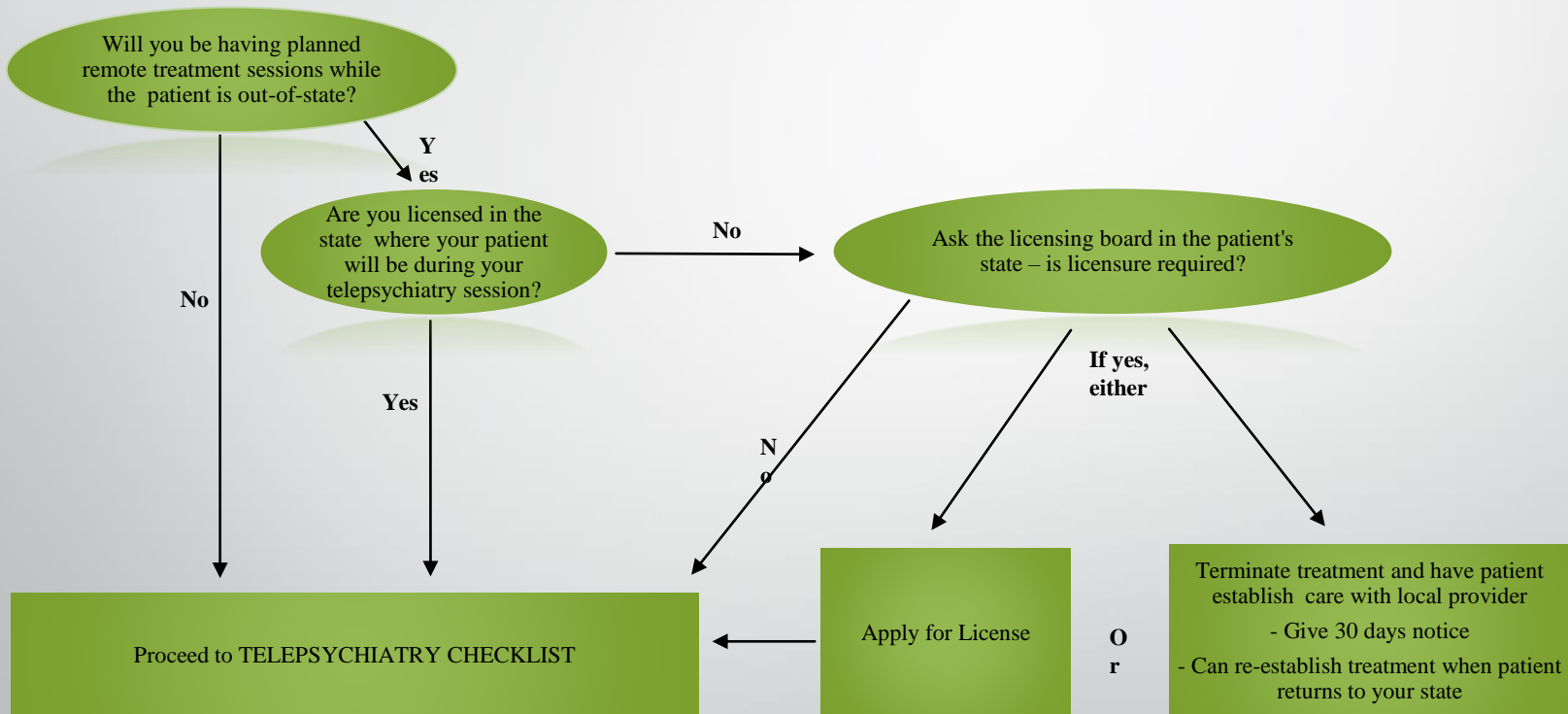
TECHNOLOGY IS ONLY A TOOL

Technology is a tool that can partially restore the lost abilities to evaluate and treat patients at a distance, but by itself, *technology cannot completely restore all abilities.*

RECAP: PRE-PANDEMIC

- Lack of information / guidance
- Inconsistent information / regulations
- Lack of awareness of information / regulations
- Misinformation
 - › RHA does NOT require in-person visit every 24 months

TREATING OUT-OF-STATE PATIENTS VIA TELEPSYCHIATRY



TELEPSYCHIATRY CHECKLIST

- ☐ I have reviewed my state's law on telemedicine, including, but not limited to:
 - ☐ In-person examination requirements
 - ☐ Prescribing requirements

- ☐ If a patient will be treated in a different state:
 - ☐ Licensure
 - ☐ I am licensed in the patient's state



STANDARD OF CARE

There is no “disaster standard of care”

Your care is always compared to care by other similar psychiatrists in similar circumstances



Handmade



[HHS A-Z Index](#)[HIPAA for Individuals](#)[Filing a Complaint](#)[HIPAA for Professionals](#)[Newsroom](#)[HHS](#) > [HIPAA Home](#) > [For Professionals](#) > [Special Topics](#) > [Emergency Preparedness](#) > Notification of Enforcement Discretion for Telehealth[HIPAA for Professionals](#)[Regulatory Initiatives](#)[Privacy](#)[Security](#)[Breach Notification](#)[Compliance & Enforcement](#)[Special Topics](#)[HIPAA and COVID-19](#)[Mental Health & Substance Use Disorders](#)[De-Identification Methods](#)[Research](#)[Public Health](#)Text Resize **A A A**

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Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency

We are empowering medical providers to serve patients wherever they are during this national public health emergency. We are especially concerned about reaching those most at risk, including older persons and persons with disabilities. – Roger Severino, OCR Director.

The Office for Civil Rights (OCR) at the Department of Health and Human Services (HHS) is responsible for enforcing certain regulations issued under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health (HITECH) Act, to protect the privacy and security of protected health information, namely the HIPAA Privacy, Security and Breach Notification Rules (the HIPAA Rules).

During the COVID-19 national emergency, which also constitutes a nationwide public health emergency, covered health care providers subject to the HIPAA Rules may seek to communicate with patients, and provide telehealth services, through remote communications technologies. Some of these technologies, and the manner in which they are used by HIPAA covered health care providers, may not fully comply with the requirements of the HIPAA Rules.

OCR will exercise its enforcement discretion and will not impose penalties for noncompliance with the regulatory requirements under the HIPAA Rules against covered health care providers in connection with the good faith provision of telehealth during the COVID-19 nationwide public health emergency. This notification is effective immediately.

Question: Can telemedicine now be used under the conditions outlined in Title 21, United States Code (U.S.C.), [Section 802\(54\)\(D\)](#)?

Answer: Yes. While a prescription for a controlled substance issued by means of the Internet (including telemedicine) must generally be predicated on an in-person medical evaluation ([21 U.S.C. 829\(e\)](#)), the Controlled Substances Act contains certain exceptions to this requirement. One such exception occurs when the Secretary of Health and Human Services has declared a public health emergency under 42 U.S.C. 247d (section 319 of the Public Health Service Act), as set forth in 21 U.S.C. 802(54)(D). Secretary Azar declared such a public health emergency with regard to COVID-19 on January 31, 2020 ... On March 16, 2020, the Secretary, with the concurrence of the Acting DEA Administrator, designated that the telemedicine allowance under section 802(54)(D) applies to all schedule II-V controlled substances in all areas of the United States. Accordingly, **as of March 16, 2020, and continuing for as long as the Secretary's designation of a public health emergency remains in effect, DEA-registered practitioners in all areas of the United States may issue prescriptions for all schedule II-V controlled substances to patients for whom they have not conducted an in-person medical evaluation, 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 his/her professional practice;**
- The telemedicine communication is conducted using an audio-visual, real-time, two-way interactive communication system; and**
- The practitioner is acting in accordance with applicable Federal and State laws.**



U. S. Department of Justice
Drug Enforcement Administration
8701 Morrisette Drive
Springfield, Virginia 22152

www.dea.gov

DEA Registrants

Dear Registrant:

The Controlled Substances Act (CSA) provides that every person who dispenses, or who proposes to dispense, any controlled substance shall obtain from the Drug Enforcement Administration (DEA) a registration issued in accordance with DEA rules and regulations. *See* 21 U.S.C. 822(a)(2). DEA may only register a person to dispense a controlled substance if that person is permitted to do so by the jurisdiction in which he or she practices. *See id.* 802(21), 823(f). Thus, unless subject to an applicable exception, DEA regulations require a practitioner to obtain a separate DEA registration in each state in which he or she dispenses a controlled substance. The DEA Administrator, however, is permitted by 21 CFR 1307.03 to grant an exception to the application of any provision in the DEA regulations codified in Chapter II of Title 21 of the CFR. This authority has been redelegated to the Assistant Administrator of the Diversion Control Division.

On January 31, 2020, the Secretary of Health and Human Services (HHS) declared a public health emergency with regard to COVID-19.¹ Many states also have declared public emergencies and granted reciprocity to neighboring states and their practitioners with regard to medical licensing requirements. As such, practitioners in such states are now permitted by state law to dispense

[https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-018\)\(DEA067\)%20DEA%20state%20reciprocity%20\(final\)\(Signed\).pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-018)(DEA067)%20DEA%20state%20reciprocity%20(final)(Signed).pdf)

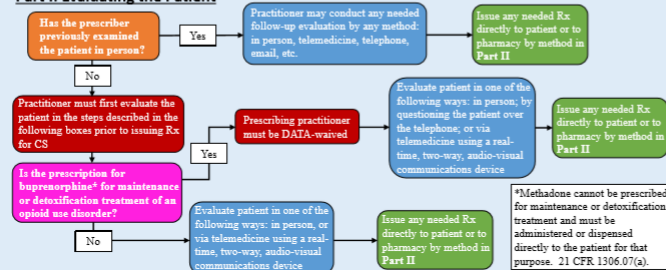
How to Prescribe Controlled Substances to Patients During the COVID-19 Public Health Emergency

In response to the COVID-19 public health emergency declared by the Secretary of Health and Human Services, the Drug Enforcement Administration (DEA) has adopted policies to allow DEA-registered practitioners to prescribe controlled substances without having to interact in-person with their patients. This chart only addresses prescribing controlled substances and does not address administering or direct dispensing of controlled substances, including by narcotic treatment programs (OTPs) or hospitals. These policies are effective beginning March 31, 2020, and will remain in effect for the duration of the public health emergency, unless DEA specifies an earlier date.

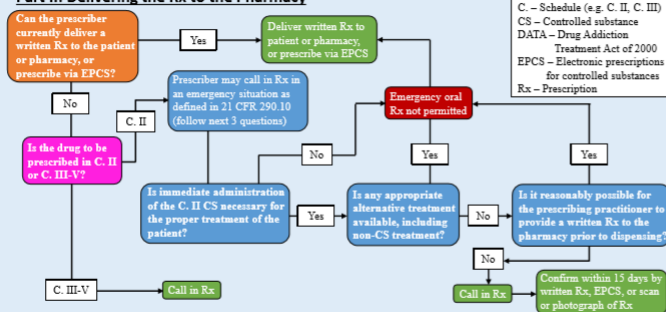
This decision tree merely summarizes the policies for quick reference and does not provide a complete description of all requirements. Full details are on DEA's COVID-19 website (<https://www.deadiversion.usdoj.gov/coronavirus.html>), and codified in relevant law and regulations.

Under federal law, all controlled substance prescriptions must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his/her professional practice. 21 CFR 1306.04(a). In all circumstances when prescribing a controlled substance, including those summarized below, the practitioner must use his/her sound judgment to determine that s/he has sufficient information to conclude that the issuance of the prescription is for a bona fide medical purpose. Practitioners must also comply with applicable state law.

Part I: Evaluating the Patient



Part II: Delivering the Rx to the Pharmacy



Guidance documents, like this document, are not binding and lack the force and effect of law, unless expressly authorized by statute or expressly incorporated into a contract, grant, or cooperative agreement. Consistent with Executive Order 13891 and the Office of Management and Budget implementing memoranda, the Department will not cite, use, or rely on any guidance document that is not accessible through the Department's guidance portal, or similar guidance portals for other Executive Branch departments and agencies, except to establish historical facts. To the extent any guidance document sets out voluntary standards (e.g., recommended practices), compliance with those standards is voluntary, and noncompliance will not result in enforcement action. Guidance documents may be rescinded or modified in the Department's complete discretion, consistent with applicable laws. Drug Enforcement Administration/Diversion Control Division DEAO75

UNITED STATES OF AMERICA



Coronavirus FAQs

UPDATED: June 9, 2020

NOTE: Please remember that we are all operating in uncharted territory and there are very few clear answers. This is a very fluid situation and recommendations may change based upon events or guidance from the federal and state governments. Please check back often for updates.

IF YOU ARE NOT INSURED THROUGH PRMS: Please do not rely on this information as more than one company's risk management thoughts. Nothing presented here is legal advice. You should check with your own risk managers.

Quick Links:

- 📌 [State Licensure Waiver Information](#)
- 📌 [Telepsychiatry Checklist \(Updated 5/21/20\)](#)
- 📌 [Preparing For What's Next - To Do List \(NEW RESOURCE\)](#)

I

COMMONWEALTH OF MASSACHUSETTS
BOARD OF REGISTRATION IN MEDICINE

POLICY 2020-01

POLICY ON TELEMEDICINE IN THE COMMONWEALTH

Amended June 25, 2020

The practice of medicine shall not require a face-to-face encounter between the physician and the patient prior to health care delivery via telemedicine. The standard of care applicable to the physician is the same whether the patient is seen in-person or through telemedicine.

ETIQUETTE

Before the encounter

- › Equipment
- › Clinical information
- › Dress
- › Noise and privacy
- › Background and lighting
- › Cultural competence

ETIQUETTE

During the encounter

- › Introductions
- › Consent
- › Framing
- › Comfort
- › Silence device and microphones (until the session starts)
- › Encourage questions

NO YELLING!!!

Patients are flashing doctors in video medicine apps, and it's a problem

- Many of the largest telemedicine apps have experienced inappropriate behavior from users
- These companies are taking steps to remedy the problem
- This issue brings up some new questions as doctor's offices transition from physical spaces to the Internet

Christina Farr | [@chrissyfarr](#)

Thursday, 20 Apr 2017 | 3:11 PM ET



ETIQUETTE

After the encounter

- › Follow-up appointments noted
- › Technical issues reported to appropriate support personnel



Policy for Certain REMS Requirements During the COVID- 19 Public Health Emergency

Guidance for Industry and Health Care Professionals

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

The Food and Drug Administration (FDA or Agency) plays a critical role in protecting the United States from threats including emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic.

FDA is issuing this guidance to communicate its temporary policy for certain risk evaluation and mitigation strategies (REMS) requirements for the duration of the public health emergency

<https://www.fda.gov/media/136317/download>

ASAM COVID-19 TASK FORCE RECOMMENDATIONS

CARING FOR PATIENTS DURING THE COVID-19 PANDEMIC

Adjusting Drug Testing Protocols



https://www.asam.org/docs/default-source/covid-19/11-adjusting-drug-testing-protocols_final.pdf?sfvrsn=5dba58c2_2



U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION DIVERSION CONTROL DIVISION

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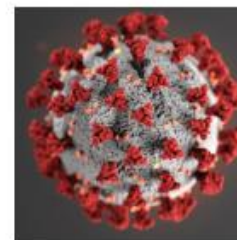
COVID-19 Information Page

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| [Records and Reports](#) | [Contacts](#) | [Important Federal Links](#) | [Important State Links](#)

The mission of Drug Enforcement Administrations (DEA), Diversion Control Division is to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs.

During this National Emergency the Diversion Control Division will continue to work with our Federal partners, DEA registrants, and their representative association to assure that there is an adequate supply of controlled substances in the United States. The DEA will also work to assure that patients will have access to controlled substances.



[Program Description](#)
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Questions and Answers

Prescriptions

DEA Policy: [Registrant Guidance on Controlled Substance Prescription Refills](#)

DEA Policy: [Exception to Separate Registration Requirements Across State Lines](#)

Registration

Registration of Emergency Temporary Sites: If you need to set up an emergency or temporary off-site location and use controlled substances, please contact DEA at Natural.Disaster@usdoj.gov. DEA will issue you a temporary registration number for each designated alternate location. This will enable the drug supply chain to continue uninterrupted and maintain patient access to needed controlled substances.

DEA Policy: [Exception to Separate Registration Requirements Across State Lines](#)

<https://www.deadiversion.usdoj.gov/coronavirus.html>

Newsroom

Coronavirus

[COVID-19 Information for SAMHSA Discretionary Grant Recipients](#)

[Media Guidelines for Bullying Prevention](#)

[Press Announcements](#)

[SAMHSA in the News](#)

[Speeches and Presentations](#)

[Infographics](#)

[Logo Use Guidelines](#)

Coronavirus (COVID-19)

SAMHSA recognizes the challenges posed by the current COVID-19 situation and is providing the following guidance and resources to assist individuals, providers, communities, and states across the country. SAMHSA stands ready to assist in any manner possible.

SAMHSA Resources and Information

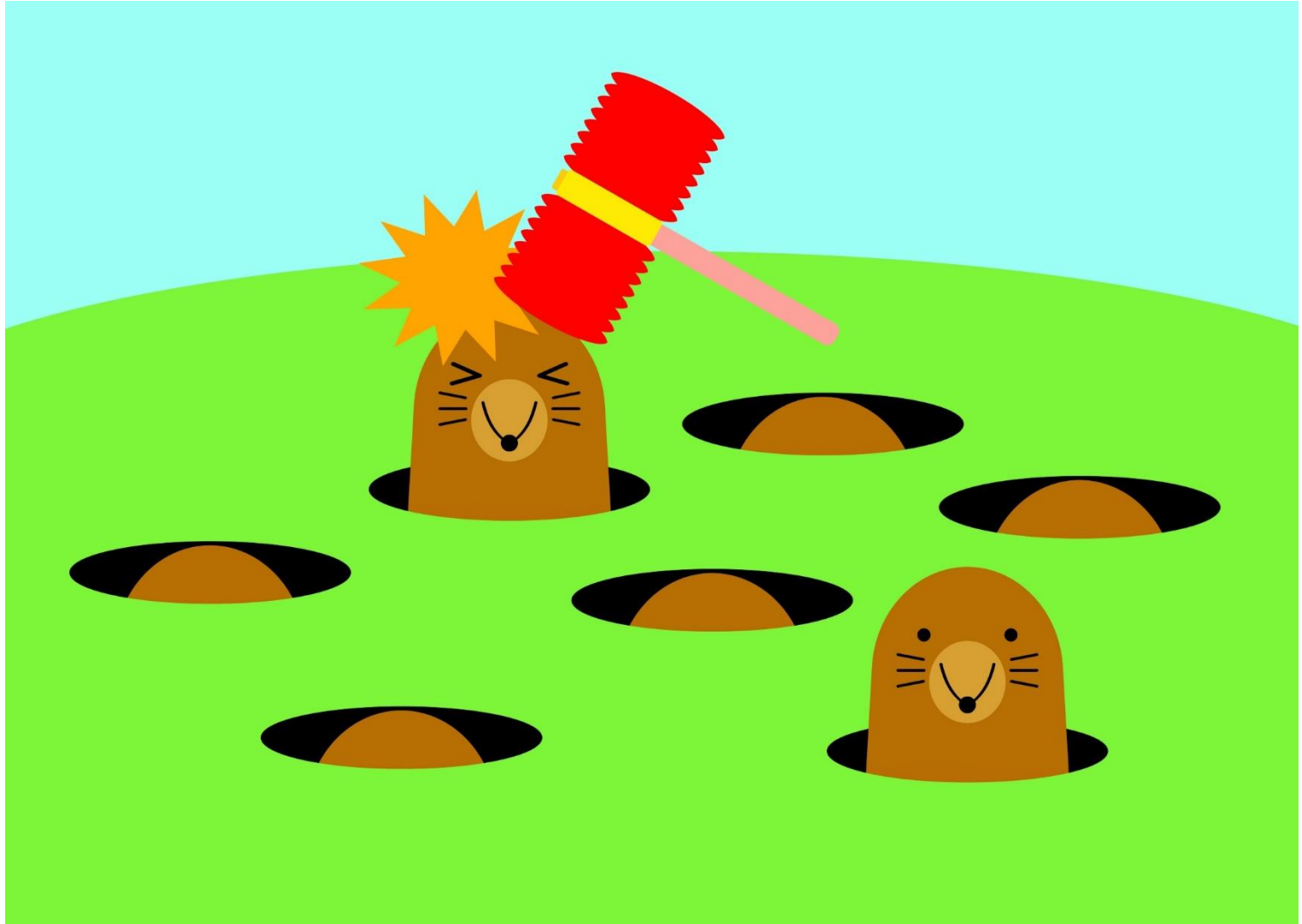
NEW: [COVID-19 Information for SAMHSA Discretionary Grant Recipients](#)

[COVID-19 Public Health Emergency Response and 42 CFR Part 2 Guidance \(PDF | 168 KB\)](#)

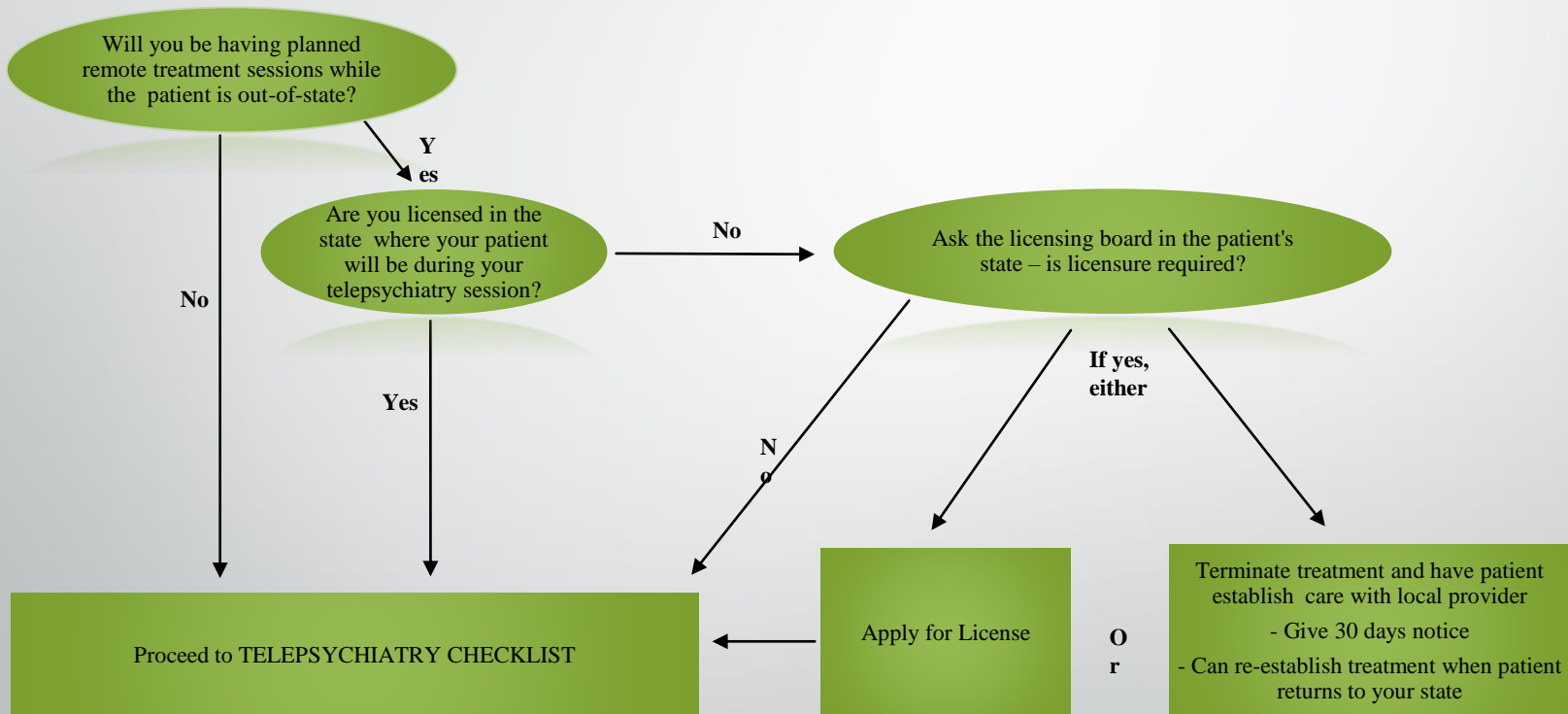
[TAP 34: Disaster Planning Handbook for Behavioral Health Treatment Programs](#)

NEW: [Considerations for the Care and Treatment of Mental and Substance Use Disorders in the COVID-19 Epidemic: March 20, 2020 \(PDF | 76 KB\)](#)

NEW: [Considerations for Crisis Centers and Clinicians in Managing the Treatment of Alcohol or](#)



TREATING OUT-OF-STATE PATIENTS VIA TELEPSYCHIATRY



TELEPSYCHIATRY CHECKLIST – MODIFIED PER CORONAVIRUS UPDATES (5/21/20)

- ☐ I have reviewed my state's law on telemedicine, including, but not limited to:
 - ☐ In-person examination requirements
 - ☐ Prescribing requirements

3/19/20: States may be relaxing some of these requirements given the need for individuals to stay home.

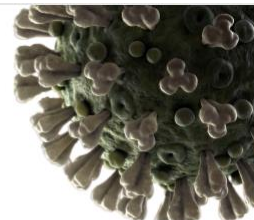
- ☐ If a patient will be treated in a different state:
 - ☐ Licensure
 - ☐ I am licensed in the patient's state, all state requirements are met (CME requirements, PMP requirements, etc...)
 - OR
 - ☐ A license in that state is not required (3/9/20)

3/19/20: States MAY be relaxing licensure requirements, but it may be only in limited circumstances, such as only to treat patients in a hospital, or only if actually treating the coronavirus.
 - ☐ Law
 - ☐ I have reviewed the law on telemedicine in the patient's state, including, but not limited to:
 - ☐ In-person examination requirements
 - ☐ Prescribing requirements

3/19/20: States have been slow to offer licensure waivers and even slower to address state treatment laws. The risk management advice is to do what you can. For example, a state may require written informed consent for the use of telemedicine. That may or may not be possible; if not possible, providers can obtain verbal consent and document that verbal consent to telemedicine.

- ☐ I am using HIPAA-compliant equipment
 - ☐ If the equipment vendor stores any patient information, I have a Business Associate Agreement from the vendor

3/19/20: The federal government has exercised "its enforcement discretion and will waive potential penalties against health care providers that serve patients through everyday communication technologies during the COVID-19 nationwide public health emergency. This exercise of discretion applies to widely available communication apps, such as FaceTime or Skype, when used in good faith for any telehealth treatment or diagnostic purpose, regardless of whether the telehealth service is directly related to COVID-19."



WHAT PHYSICIANS NEED TO KNOW

Working from home during COVID-19 pandemic

During the COVID-19 pandemic, many physicians are working from home, using their personal computers and mobile devices to help care for patients. Fortunately, technology can allow physicians and care teams to do much of what they could do at the medical office, remotely. Telemedicine is a powerful tool that spans a continuum of technologies and offers new ways to deliver care. Many electronic health record (EHR) systems allow you to connect over the Internet just as if you were in the clinic. While you are doing your part to help during the COVID-19 pandemic, the American Medical Association (AMA) and American Hospital Association (AHA) want to ensure you have resources to help keep your work environment safe from cyber-threats that could disrupt your practice, the hospital, or negatively impact your patients' safety and well-being.

Your Home Personal Computer (PC)

Your home computer, whether it be a Windows or Mac, laptop or desktop, is susceptible to cyber threats. It is important to take steps to keep your home office as resilient as your medical practice. We are learning of increased security threats to medical data due to the pandemic. Many cyber criminals are taking advantage of clinician interest in COVID-19 to infect practices', and hospitals' computers and networks with the hope of stealing or holding medical records for ransom.

To help protect you and your patients, the AMA has compiled a [Checklist for Computers](#), which is a non-exhaustive list of **actions you should take immediately** to strengthen your home computer and network.

- Watch out for these common threats:

<https://www.aha.org/system/files/media/file/2020/04/cybersecurity-work-from-home-covid-19.pdf>



Date: Originally Posted May 5, 2020; Updated May 29, 2020
Re: COVID-19 Related Opinions of the APA Ethics Committee

APA's Ethics Committee invites members to seek advice on ethical dilemmas they face in practice. The Ethics Committee continues to receive questions related to ethical practice during the COVID-19 pandemic. Below are responses to questions we have recently received. If you have an ethics question, please submit your question to apaethics@psych.org and the APA Ethics Committee will answer it. Please do not submit questions related to the facts of any actual or pending ethics complaints.

QUESTION 1:

When we use unfamiliar technologies (e.g. telehealth technologies) to provide treatment during COVID-19, what considerations should psychiatrist be aware of to ensure disruptions of care are minimized?

ANSWER:

The availability of technology is incredibly helpful during this public health crisis as it allows psychiatrists and patients to continue treatment while apart because of physical distancing. While using these technologies, psychiatrists have an ongoing ethical responsibility to maintain patient confidentiality and





TELEPSYCHIATRY CHECKLIST – MODIFIED PER CORONAVIRUS UPDATES (9/2/20)

- ☐ I have reviewed my state's law on telemedicine, including, but not limited to:

- ☐ In-person examination requirements
- ☐ Prescribing requirements

3/19/20: States may be relaxing some of these requirements given the need for individuals to stay home.

- ☐ If I'm located in a state where I'm not licensed, and I'm not seeing any patients located in that state:

- ☐ I have confirmed with that state's licensing board that no license is necessary to treat out-of-state patients.



LOOKING FORWARD

Technology Considerations for the Rest of 2020

In the months since the United States first declared a public health emergency due to COVID-19, hospitals and physician practices have learned many lessons. Notably, the pandemic quickly increased most Americans' reliance on digital tools, including digital health technologies like telemedicine, which brought increased industry focus on how physicians and hospitals keep patients' protected health information (PHI) private and secure. *Privacy and security are distinct, but closely interrelated. It is not enough for medical practices and hospitals to invest in one but not the other. Fortunately, the concepts are mutually reinforcing, meaning that many actions that are taken to bolster security of patient information will also better protect the privacy of that information.*

The American Medical Association (AMA) and American Hospital Association (AHA) have monitored a variety of technology issues associated with the novel coronavirus and developed a range of resources to assist their members, including our joint resource, [What Physicians Need to Know: Working from home during the COVID-19 pandemic](#). Now, as practices reopen, and hospitals around the country prepare for a second wave of COVID-19 infections coinciding with cold and flu season, our organizations are providing this update on steps physicians should take to prepare for the coming months

Cybersecurity

Risks and Vulnerabilities Update

The COVID-19 pandemic has dramatically changed our way of life and that of the world, including bringing a greater number of people together virtually. However, there is one group that views the pandemic as an opportunity to exploit our virtual community for illicit purposes – cyber criminals.

<https://www.ama-assn.org/system/files/2020-10/ama-aha-technology-considerations.pdf>

IMPORTANT UPDATE
from PRMS



Here is a transcript of a call between a psychiatrist (P) and her Risk Manager (RM):

P: I need to know how to prescribe for my patient who is attending college in another state.

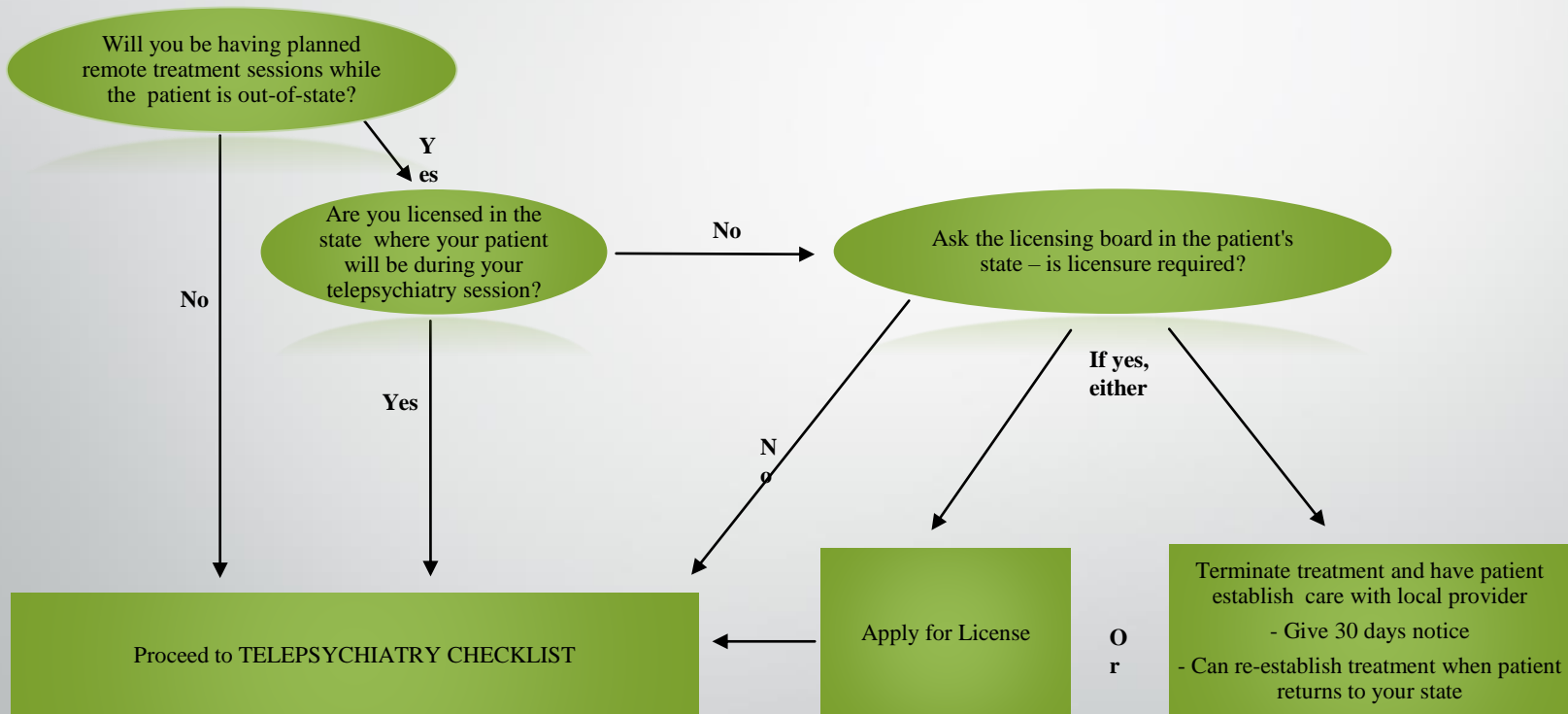
RM: Are you having remote sessions with this patient?

P: Yes, I am continuing to treat while he is away at school.

RM: Did you check with the licensing board of the state where your patient attends college to determine if you need a license in that state?

P: No - I'm just continuing to treat my patient that I've seen since he was a child.

TREATING OUT-OF-STATE PATIENTS VIA TELEPSYCHIATRY



COVID-19: A physician guide to keeping your practice open

Updated Aug. 12, 2020

As physicians reopen and strive to keep open their practices during the COVID-19 pandemic, measures to limit the spread of the SARS-CoV-2 virus to patients, caregivers, staff and themselves are just as, if not more, necessary as ever.

It will be those measures, clearly communicated, consistently implemented and updated as new evidence becomes available, that will engender in patients the confidence they need to seek care. Furthermore, as instances have been reported in which fear of exposure to the virus has resulted in adverse outcomes for patients who delayed or avoided seeking necessary care, the importance of ensuring access to care and addressing patients' concerns about risk of seeking care has been reaffirmed.

The U.S. Centers for Disease Control and Prevention (CDC) has provided a [framework](#) within which non-COVID-19 care can be delivered. The Centers for Medicare & Medicaid Services (CMS) also has published and updated its [guide](#) (PDF) for reopening facilities to provide non-emergent, non-COVID-19 care.

<https://www.ama-assn.org/delivering-care/public-health/covid-19-physician-guide-keeping-your-practice-open>

Reopening Health and Human Services in Massachusetts

Health and Human Services reopening plans and guidance

During the [COVID-19 public health emergency](#), in order to ensure Massachusetts' health care system had the capacity to address the pandemic, some health care services and procedures were limited or temporarily put on hold, while many services were conducted remotely using telehealth. Emergency services and other essential health and human services continued during this time.

Phase 1: On May 18, the Commonwealth [issued new guidelines to hospitals and health care providers](#) in accordance with the state's [four-phase reopening plan](#), to allow some non-emergency procedures or deferred care that may now need attention. Hospitals and Community Health Centers began this reopening May 18, and all other providers began on May 25.

Phase 2: On June 6, the Commonwealth issued new guidelines allowing health care providers at the start of Phase 2 to incrementally resume in-person elective, non-urgent

Renewal of Determination That A Public Health Emergency Exists

As a result of the continued consequences of the Coronavirus Disease 2019 (COVID-19) pandemic, on this date and after consultation with public health officials as necessary, I, Alex M. Azar II, Secretary of Health and Human Services, pursuant to the authority vested in me under section 319 of the Public Health Service Act, do hereby renew, effective October 23, 2020, my January 31, 2020, determination, that I previously renewed on April 21, 2020 and July 23, 2020, that a public health emergency exists and has existed since January 27, 2020, nationwide.

<https://www.phe.gov/emergency/news/healthactions/phe/Pages/covid19-2Oct2020.aspx>

FEDERAL WAIVERS REMAIN PLACE THROUGH PHE

- HHS
 - Telemedicine technology
- DEA
 - In-person visit requirement
 - DEA registration in patient's state



Preparing for What's Next - To Do List

JUNE 2020

NOTE: We are operating in uncharted territory and there are very few clear answers currently. This is a very fluid situation and the risk management recommendations below may change. This document will be updated on our FAQ page (www.PRMS.com/FAQ), and should be checked regularly. Nothing presented here is legal advice.

While we do not know exactly what will happen next in terms of the country re-emerging from the COVID-19 Public Health Emergency (PHE), psychiatrists should be prepared to address at least the following issues:

1. RE-OPENING YOUR PSYCHIATRIC OFFICE

In addition to your local community guidelines, review guidelines and best practices from the AMA, MGMA (Medical Group Management Association), CMS, and others.

Tip: Links to these resources are in our FAQs.

2. FOR PATIENTS THAT REMAINED LOCAL, DETERMINE WHETHER THEY NEED TO BE SEEN IN-PERSON, REMOTELY, OR A COMBINATION OF BOTH

This determination should be based on your assessment of the patients' clinical needs, not on the patients' preference for telepsychiatry.

3. FOR PATIENTS CURRENTLY OUT-OF-STATE, DETERMINE IF THEY HAVE IMMINENT PLANS TO RETURN TO YOUR AREA

Manage patient expectations – let them know that the rules may be changing soon and you may not be allowed by law to continue to treat remotely

person visits, informed consent, documentation, etc. If your patient's state does not have such laws, follow the telemedicine guidelines developed by the Federation of State Medical Boards.

PRMS will help our insureds find this state information.

7. IF AFTER THE WAIVER ENDS, YOU ARE NOT ABLE TO CONTINUE TREATING THE OUT-OF-STATE PATIENT (I.E. FULL LICENSURE IS REQUIRED), TERMINATE TREATMENT

Although this should be done quickly, do not abandon your patient– consider giving 30 days' notice.

8. IF AFTER THE WAIVER ENDS YOU WANT TO CONTINUE TREATING YOUR PATIENT REMOTELY AND HAVE DETERMINED THAT YOU ARE IN COMPLIANCE WITH LICENSING REQUIREMENTS, ENSURE YOU ARE ALSO IN COMPLIANCE WITH THE PATIENT'S STATE'S PRESCRIBING LAWS

There may be specific state laws, particularly for controlled substances.

You should also register with and use, to the extent possible, the state prescribing drug monitoring program.

9. IF YOU ARE PRESCRIBING CONTROLLED SUBSTANCES FOR OUT-OF-STATE PATIENTS, BE ALERT TO WHEN HHS DECLARES THE END TO THE PHE

The current PHE declaration is set to expire in January. It can be revoked earlier, or extended.

Tip: PRMS will be tracking this in our FAQs.







U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION

DIVERSION CONTROL DIVISION

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Rules - 2020

A. In-Person Medical Evaluation Requirement

One of the primary ways in which the Act combats the use of the internet to facilitate illegal sales of pharmaceutical controlled substances is by mandating, with limited exceptions, that the dispensing of controlled substances by means of the internet be predicated on a valid prescription issued by a practitioner who has conducted at least one in-person medical evaluation of the patient. While the lack of an in-person medical evaluation has always been viewed as highly probative evidence that a prescription has been issued outside of the usual course of professional practice and for other than a legitimate medical purpose, the Act makes it unambiguous that it is a per se violation of the CSA for a practitioner to issue a prescription for a controlled substance by means of the internet without having conducted at least one in-person medical evaluation, except in certain specified circumstances. However, as Congress expressly stated under the Act, the mere fact that the prescribing practitioner conducted one in-person medical evaluation does not demonstrate that the prescription was issued for a legitimate medical purpose within the usual course of professional practice. Even where the prescribing practitioner has complied with the requirement of at least one in-person medical evaluation, a prescription for a controlled substance must still satisfy the longstanding requirement of federal law that it must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.^{2\}

^{2\} **21 CFR 1306.04(a)**; United States v. Moore, 423 U.S. 122 (1975). This requirement has been a part of federal law since the Harrison Narcotic Act of 1914. Id. at 131. For a detailed explanation of the "legitimate medical purpose requirement," see 71 FR 52716, 52717 (2006 DEA policy statement).

https://www.deadiversion.usdoj.gov/fed_regs/rules/2020/fr0930_2.htm



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Rules - 2020

V. Section-by-Section Discussion of the Final Rule

As discussed above, DEA is adopting the interim final rule as a final rule without change, except for a technical amendment further explained below and certain minor changes already made by intervening rules. Thus, the interim final rule's more detailed discussion of its provisions generally remains valid. See 74 FR 15610-15613. In brief, however, the final rule consists of the following provisions, all of which were already added to the Code of Federal Regulations by the interim final rule.

In **part 1300** (definitions), **Sec. 1300.04**, containing definitions relating to the dispensing of controlled substances by means of the internet, was added by the interim final rule and remains unchanged. These definitions are from the definitions contained in the Act and include definitions of the following terms: "covering practitioner," "deliver, distribute or dispense by means of the internet," "filling new prescriptions for controlled substances in Schedule III, IV, or V," "homepage," "in-person medical evaluation," "internet," "online pharmacy," "practice of telemedicine," "refilling prescriptions for controlled substances in Schedule III, IV, or V," "valid prescription," and the temporary definition of "practice of telemedicine." \16\ As discussed in the interim final rule and as authorized by the Act, Sec. 1300.04 adds two exceptions to the definition of an online pharmacy beyond the eight exceptions provided for in the Act. See 21 CFR 1300.04(h); **21 U.S.C. 802(52)(B)**.

\16\ As explained in the interim final rule, the Ryan Haight Act provided two definitions of the "practice of telemedicine," a temporary definition and a permanent definition. See 74 FR 15603; Public Law 110-425, sec. 3(j). The interim final rule incorporated both of these definitions, with the permanent definition, **21 CFR 1300.04(i)**, becoming effective on January 15, 2010, and the temporary definition, 21 CFR 1300.04(j), effective before that date. The permanent definition of the "practice of telemedicine" includes practice "conducted by a practitioner who has obtained from the Administrator a special registration under section 311(h) of the Act (**21 U.S.C. 831(h)**)." 21 CFR 1300.04(i)(5); **21 U.S.C. 802(54)(B)**. The Act, as amended, contemplates that DEA will issue regulations effectuating this telemedicine special registration provision by October 24, 2019. 21 U.S.C. 831(h)(2). DEA will further address the definition and requirements of telemedicine in future rulemaking.

https://www.deadiversion.usdoj.gov/fed_regs/rules/2020/fr0930_2.htm

[illegible]

WHEN CONSIDERING TELEPSYCHIATRY – PATIENT SELECTION

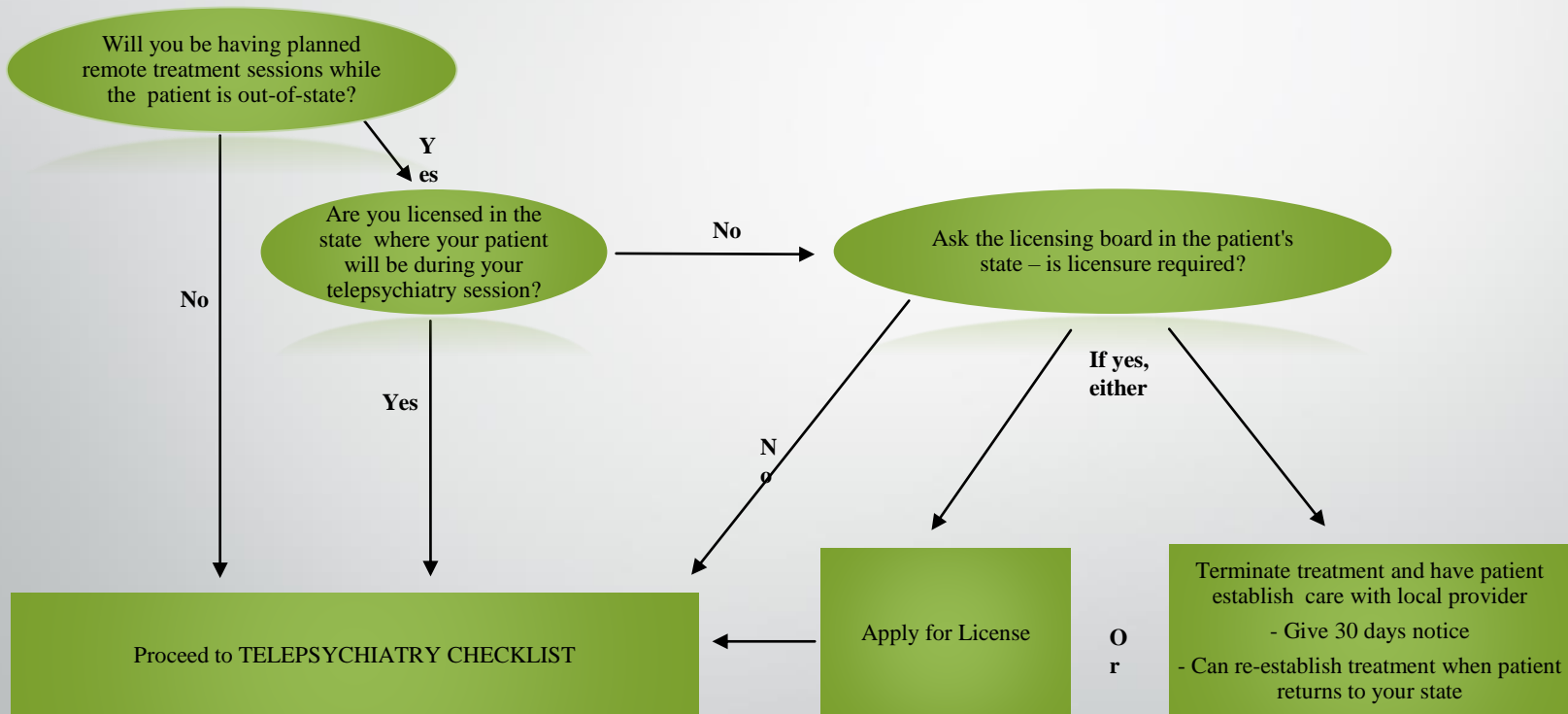
- What conditions do you routinely treat?
- Which of these could you treat remotely
 - Will lost abilities be a problem?
 - Is there someone local to assist as needed?
- Where is patient receiving services?
- Can you treat condition in this environment?

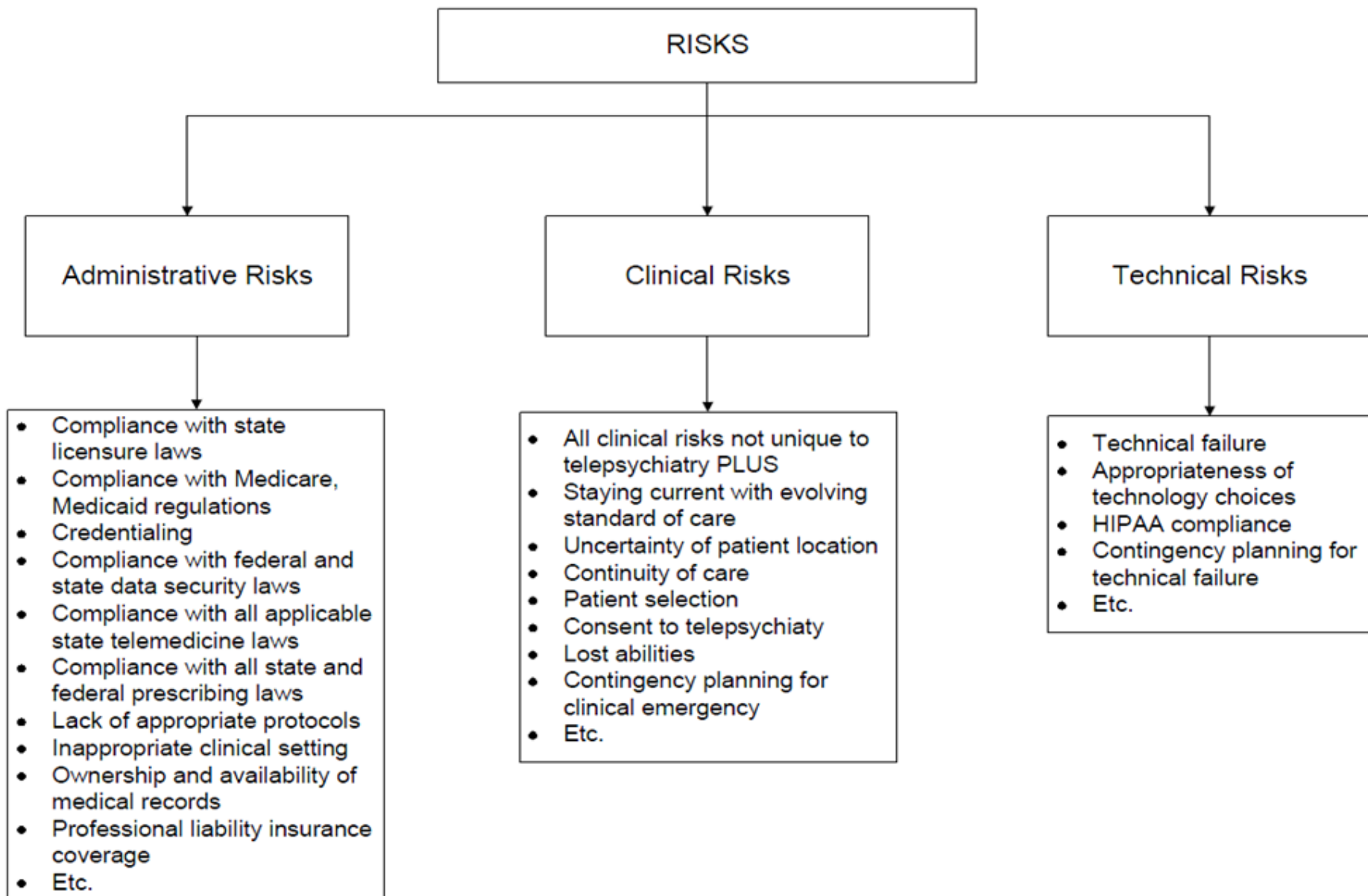
PATIENT SELECTION – NY OMH’S GUIDANCE

Process for assessment of appropriateness should include the following considerations:

- Appropriateness based on clinical situation
- Patient’s awareness, familiarization with the process
- Concerns regarding instability, suicidal ideation, violence, etc.
- Symptoms that could worsen with telepsychiatry (psychosis with ideas of reference, paranoid/delusions related to technology, etc.)
- Medical issues
- Cognitive/sensory concerns
- Cultural
- Whether or not a patient should be accompanied by a staff member during telepsychiatry sessions
- Services provided to patients under age 18 (refer to the AACAP Practice Parameter)

TREATING OUT-OF-STATE PATIENTS VIA TELEPSYCHIATRY





RISK MANAGEMENT STRATEGIES

Collect Information

- About relevant licensure laws
- About laws (treatment, telemedicine, etc.) from patient's state
- About reimbursement
- About HIPAA compliance
- About telepsychiatry technology set-ups
- About professional liability insurance coverage
- From patient
- From other providers
- From state PM
- Etc.

Communicate

- With patient
- With all treating providers
- Consent to telepsychiatry
- Protocols
- Etc.

Carefully Document

- Contract with third party vendor
- Business Associate Agreement
- Clinical record
- Protocols
- Etc.

RISK MANAGEMENT ADVICE - WHEN CONSIDERING TELEPSYCHIATRY

- Define your telepsychiatry endeavor
 - › What you want to do
 - › What technology you want to use
- Determine all relevant laws and other standard of care factors
- Evaluate your ability to comply with legal requirements
 - › E.g., Ensure all relevant medical boards allow you to do the exact telepsychiatry activities you want to do and with the technology you want to use
 - Licensure requirements
 - Physical examination requirements
 - Etc.
- Understand the importance of the location of the patient, both for legal and clinical reasons

RISK MANAGEMENT ADVICE – WHEN CONSIDERING TELEPSYCHIATRY

- Understand that the standard of care does not change with technology
- Evaluate the impact of your proposed telepsychiatry endeavor on your ability to meet the normal standard of care
 - › In addition to meeting all care issues not unique to psychiatry, there are additional care issues related to telepsychiatry that must also be met
 - › Understand that technology is a tool that can partially restore lost abilities to evaluate and treat patients at a distance, but technology itself cannot completely restore all lost abilities
 - › Formulate strategies to:
 - Comply with all applicable laws
 - Restore lost abilities where possible
 - Avoid situations where needed abilities cannot be restored
- Inform your Underwriter of your planned telepsychiatry activities

RISK MANAGEMENT ADVICE - WHEN DOING TELEPSYCHIATRY

- Consider what will be “lost” when treating individual patients re:
 - › Communication
 - › Ability to diagnose and treat
- Ensure the ability to treat individual patients within the standard of care
 - › Carefully evaluate whether a particular form of telepsychiatry is appropriate for a given patient
 - At the beginning of treatment
 - AND at clinically significant events
 - AND periodically as treatment progresses
 - › Determine whether and how the particular form and method of treatment will help the patient progress toward legitimate treatment goals
- Ensure patients have a basic understanding of the technology being used and appreciate its limitations

RISK MANAGEMENT ADVICE - WHEN DOING TELEPSYCHIATRY

- Prepare for possible emergencies by having patient addresses and local emergency services numbers available
- Utilize a consent form wherein the patient acknowledges
 - › the possibility of a privacy / security breach
 - › the possibility that medical conditions may not be able to be observed remotely
- Include in documentation of session
 - › that session was conducted via telepsychiatry
 - › why this method was chosen for this patient
 - › why it continues to be an appropriate treatment option
- Continually re-evaluate physician and patient level of satisfaction

OBJECTIVES - RECAP

Explain at least two temporary modifications to the regulatory requirements for telepsychiatry, based on the pandemic

- HHS – telemedicine platform does not have to be HIPAA-compliant
- DEA – prescribing controlled substances
 - › In-person visit prior to prescribing is not required
 - › DEA registration in patient's state, if different, is not required
- FDA – REMS requirement for lab testing is up to prescriber's clinical judgment
- States - licensure may be waived

OBJECTIVES - RECAP

Discuss how the pandemic affects the standard of care for the delivery of psychiatric services

- No “disaster standard of care” is needed
 - › Standard of care is flexible
 - › Your care is compared to a similar psychiatrist in similar situations
- Standard of care for telemedicine is the same as for in-person treatment
 - › How you meet it may differ

OBJECTIVES - RECAP

Understand the various possible implications when the federal government's Public Health Emergency ends

- Need HIPAA-compliant telemedicine platform
 - › BAA from vendor
- Need in-person visit before prescribing controlled substances
 - › Unless limited exception applies
- Likely need DEA registration in both your state and patient's state, if different, to prescribe controlled substances
- Telephone evaluations for bupremorphine may no longer be allowed

