PROFESSIONAL LIABILITY EXPOSURES IN CLINICAL PRACTICE AND RISK MANAGEMENT

Wellspan Philhaven

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Professional Risk Management Services (PRMS)

I have no relevant financial relationships with commercial interests.

Nothing I say today is legal advice.

OBJECTIVES

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

- Identify the highest exposure cases in terms of frequency and severity
- List the critical components of suicide risk assessments
- Discuss common pitfalls of suicide risk assessments
- Assess and document suicidal risk initially and at critical junctures in treatment
- Document the decision-making process when assessing and treating patients at risk for suicide or violence
- Explain the risks when prescribing controlled substances
- Implement at least one strategy for minimizing risks associated with prescribing controlled substances
- Discuss, recognize, and address potential legal and clinical hurdles in telemedicine practice

OBJECTIVES *(CONT'D)*

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

- Identify the factors that evidence the standard of care in telepsychiatry
- Utilize methods for maximizing patient care and minimizing risk exposure during the telemedicine encounter
- Recognize documentation risk areas inherent in EHR systems
- Understand the significance of documenting the reasoning behind clinical decision-making
- Understand liability exposure and implement strategies for minimizing risks associated with supervision of clinical and non-clinical staff
- Discuss current state law related to medical marijuana
- Understand the federal government's position, and its impact on psychiatrists
- Identify various risk management strategies to minimize professional liability exposure

AGENDA

November 3

- The state of professional liability: an update
- Patients at risk of suicide
- Psychopharmacology
- Telepsychiatry

November 10

- Collaboration & liability for the acts of others
- Electronic health records
- Medical marijuana

THE STATE OF PROFESSIONAL LIABILITY: AN UPDATE

PSYCHIATRY IS A LOW-RISK SPECIALTY

- Low risk activities
  - Forensic practice
  - Child and adolescent practice
  - Psychoanalysis

GREATEST EXPOSURE

Greatest Professional Liability Exposure - Frequency

For psychiatrists:

- Patient suicide / attempted suicide
- Psychopharmacology

GREATEST EXPOSURE

Greatest Professional Liability Exposure - Severity

Cases involving significant permanent neurological or physical injuries that result in need for life-long care

- Financial costs associated with providing life-long care
- Loss of potential income
- Pain and suffering awards

PSYCHIATRY CLAIMS

PRMS Experience

- 77% of claims close without indemnity payment or by dismissal or summary judgment
- 20% of claims settle
- 3% go to trial
  - Greater than 99% defense verdicts

Professional Risk Management Services (PRMS)

Cause of Loss – Claims and Lawsuits

2010 – 2019

Primary Allegation	All Aged Patients
Incorrect Treatment	31%
Medication Issues	21%
Suicide/Attempted Suicide	13%
Other	10%
Incorrect Diagnosis	4%
Hospital Commitment / Discharge	7%
Breach of Confidentiality	5%
Improper Supervision	4%
Boundary Violation	2%
Forensic (expert testimony, IMEs, etc.)	1%
Duty to Warn / Protect	1%
Abandonment	1%

Notes:

- "Primary allegation" is the main allegation by plaintiffs' attorneys of what the psychiatrist did wrong
- "Incorrect treatment" will represent a high percentage of cases because plaintiffs' attorneys often use a broad, general allegation initially; this category includes all types of cases, including suicide and psychopharmacology
- The category labeled "Improper Supervision" refers to supervision of patients as well as of other providers

Elements Of A Lawsuit

Duty of Care

The physician owed a duty of care to the patient (to meet the standard of care)

Breach of Duty

The physician was negligent (the care provided fell below the standard of care)

Damages

The patient suffered an adverse outcome (injury)

Causation

The patient’s damages were a direct result of the physician's negligence

DETERMINING THE APPLICABLE STANDARD OF CARE

The degree of skill, care, and diligence exercised by members of the same profession/specialty practicing in light of the present state of medical science

DETERMINING THE APPLICABLE STANDARD OF CARE

Many items may be admissible, along with expert testimony, to determine the issue of standard of care. The following items could be relied upon as ***evidence of*** the appropriate standard of care:

- Statutes – federal and state
- Regulations – federal and state
- Case law – federal and state
- Other materials from federal and state regulatory agencies – state medical boards, DEA, FDA, etc.
    - Rules / Guidelines / Policy Statements
- Authoritative clinical guidelines

DETERMINING THE APPLICABLE STANDARD OF CARE

- Policies and guidelines from professional organizations
- Learned treatises
- Journal articles
- Research reports
- Facility's own policies and procedures
- PDR recommendations
- Drug manufacturer recommendations

THE STANDARD OF CARE AND PRACTICE GUIDELINES

- Guidelines are not, by themselves, the standard of care.
- Guidelines are just one piece of evidence that the judge or jury will use to define the applicable standard of care.
- If deviate, document and justify your reasoning.

NEGLIGENCE

The failure to meet the standard of care; negligence is accidental

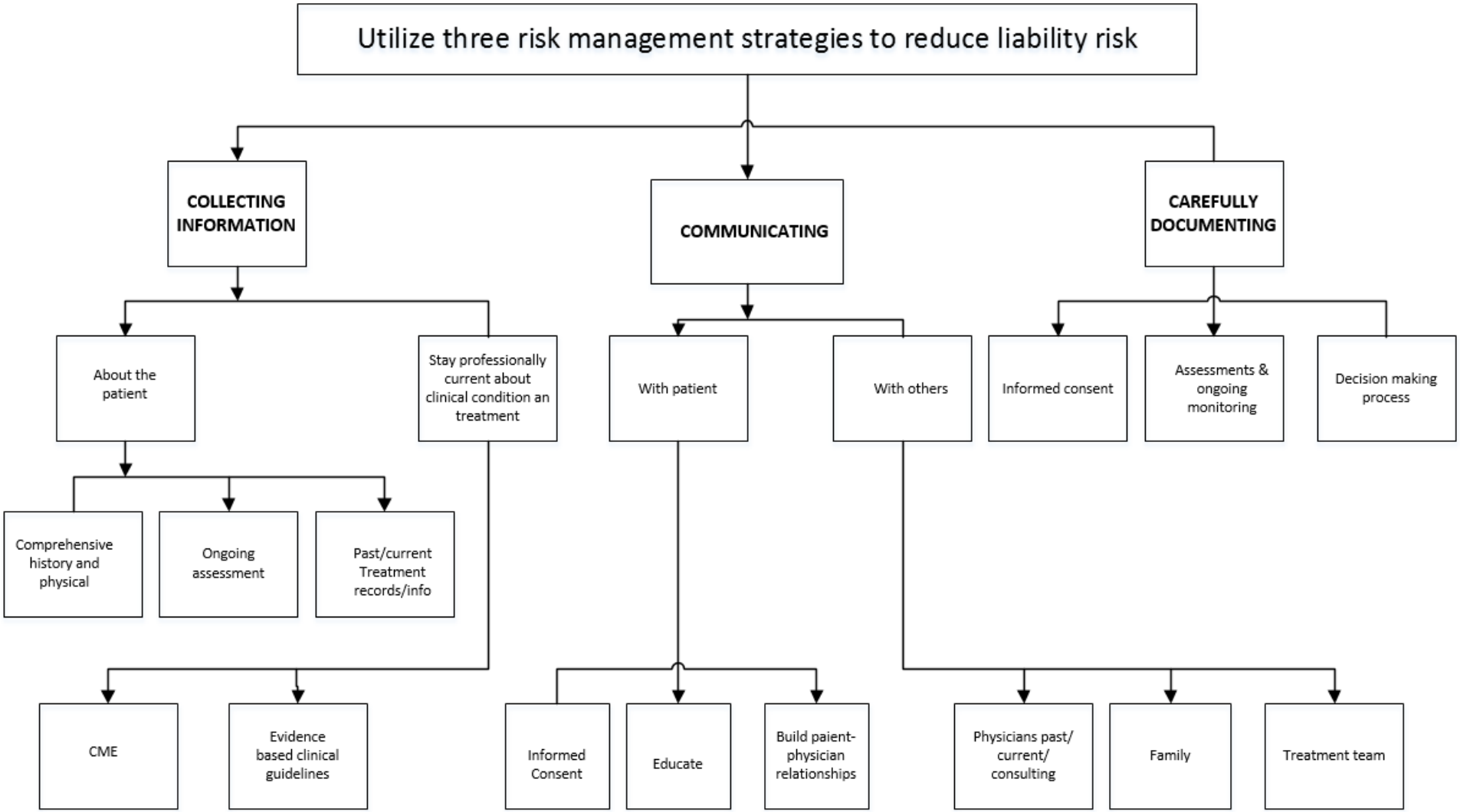
MEDICAL/PROFESSIONAL MALPRACTICE

The act(s) or continuing conduct of a provider which does not meet the standard of care AND results in injury/damage to the patient; such error does not include the exercise of professional judgment even when the results are detrimental to the patient.

WHY PATIENTS SUE

- Poor rapport and poor communication between the patient, provider, and staff
- Poor quality of care
- Poor outcome
- Unrealistic expectations regarding treatment
- Used as coping mechanism by patient and/or family
- Litigious society
- Greed

3 Cs of RISK MANAGEMENT



PATIENTS AT RISK OF SUICIDE

CASE LAW

- "The science of psychiatry represents the penultimate grey area. Numerous cases underscore the inability of psychiatric experts to predict, with any degree of precision, an individual's propensity to do violence to himself or others"
- "Indeed, psychiatrists themselves would be the first to admit that however desirable an infallible crystal ball might be, it is not among the tools of their profession"

(Paddock v. Chacko, 1988)

ASSESSING RISK

- No one can predict future dangerous behavior with absolute certainty
- Approaches to risk assessment:
  - **Actuarial**
    - Uses information derived from group data instead of an individualized assessment of dangerousness
  - **Clinical**
    - Individualized assessment based solely on psychiatrists' intuition, experience, and clinical orientation
  - **Structural clinical judgment (preferred)**
    - Psychiatrist uses a list of empirically validated risk factors known to be associated with violence
    - Psychiatrist uses clinical judgment to weigh importance of risk factors

(Phillips, 2012)

ASSESSING RISK

- You have to ask about access to firearms
  - APA Guidelines: because of the increased risk, mental health providers should routinely ask patients about suicidal thoughts, intents, or plans, including this question:
    - "Do you have any guns or weapons available to you?"
  - "Evidence indicates that the presence of firearms in the home is a risk factor for suicide"
  - "Miller and Hemmenway suggested that the availability of firearms increases the risk of suicide for three reasons:
    - Many suicidal acts are impulsive
    - Many suicide crises are self-limiting
    - And guns are common in the US and lethal
  - They contend 'restriction of access to lethal means is one of the few suicide prevention policies with proven effectiveness'"

(Cook et al, 2012)

PATIENTS AT RISK FOR SUICIDE

Cannot predict suicide

but

risk of suicide may be foreseeable

STANDARD OF CARE – SUICIDE CASES

* Suicide risk is identified and treated appropriately *

Standard of care factors:

- Whether there was adequate identification and evaluation of suicide risk indicators and protective factors for the patient with suicidal behaviors
- Whether a reasonable treatment plan was developed based on the assessment of the patient's clinical needs
- Whether the treatment plan was appropriately implemented and modified based on an ongoing assessment of the patient's clinical status
- Whether the provider was professionally current regarding the assessment and treatment of patients with suicidal behaviors
- Whether documentation was adequate to support that appropriate care was provided in terms of the assessment, treatment, and ongoing monitoring of the patient

RISK MANAGEMENT STRATEGY #1

Collecting Information

COLLECTING INFORMATION *ABOUT THE PATIENT*

- Assess patients at significant points in treatment
- Assessment is ongoing
  - Consider the possibility of comorbid conditions
    - Substance use
    - Medical conditions
- Try to get prior records; if can't, document attempts
- Obtain collateral information from family and significant others
- Inquire about access to weapons
- Consistently utilize specific, reputable suicide assessment and treatment methodology/resource

CRITICAL COMPONENTS – SUICIDE RISK ASSESSMENT

- Identify risk factors
  - Note those that can be modified
- Identify protective factors
- Inquire as to the patient's suicidal ideation, intent, plan
- Document the assessment
- Use the information gathered to determine the risk level and treatment plan

APA PRACTICE GUIDELINES FOR THE PSYCHIATRIC EVALUATION OF ADULTS

ASSESSMENT OF SUICIDE RISK

Statement 1: contents of initial psychiatric evaluation

Statement 2: contents to include if current suicidal ideas are reported

Statement 3: contents to include if prior suicide attempts are reported

Statement 4: document estimation of patient's suicide risk

(APA, 2016)

COMMON PITFALLS – SUICIDE RISK ASSESSMENT

- No assessment
- Delegating risk assessment
- Documenting assessment
- “Gut” assessments
- Risk assessment forms
- “No harm contract”

(Simon, 2011)

COMMON PITFALLS – SUICIDE RISK ASSESSMENT

- Assuming self report is accurate
- Using black and white thinking

(Nau, 2014)

COLLECTING INFORMATION *ABOUT THE PATIENT*

Consider what patients in the digital age can do:

- Use social networking – Facebook, chat rooms, blogs
- Watch YouTube
- Become addicted to pornography online
- Post sexually suggestive content online
- Sexting
- Be online targets for sex
- Bully online
- Be bullied online
- Gamble online
- Online gaming – can be very violent
- Search online for information about dangerous behaviors

COLLECTING INFORMATION
STAYING PROFESSIONALLY CURRENT

- Know the criteria for involuntary hospitalization
- Be familiar with reputable treatment guidelines
  - Document reasons for deviating

RISK MANAGEMENT STRATEGY #2

Communicating

COMMUNICATING

- Do not rely solely on “no harm contracts”
  - No legal force
  - But … may be one part of a comprehensive treatment plan
- Consider discussing patient internet activities
- Risk reduction planning should be completed with patient involved
- Educate patient on services available

COMMUNICATING

- Communicate with other healthcare professionals
  - Do not hesitate to seek consultation or second opinion
  - Other treating providers, covering providers

- Communicate with family and significant others
  - Involve and educate
  - Stress responsibility
  - Access to weapons

COMMUNICATING

- Remember: patient safety is *exception* to confidentiality
- Consider alerting family members / significant others to risk of suicide without patient authorization when:
  - The risk is significant
  - They do not seem to be aware of the risk
  - They might contribute to patient's safety

RISK MANAGEMENT STRATEGY #3

Carefully Documenting

DOCUMENTING

APA Practice Guideline for the Treatment of Patients With Suicidal Behaviors.

From Part A (v); Table 9- General Risk Management and Documentation Considerations in the Assessment and Management of Patients at Risk of Suicide

… Careful and attentive documentation, including:

- Risk assessments
- Record of decision-making processes
- Descriptions of changes in treatment
- Record of communications with other clinicians
- Record of telephone calls from patients or family members
- Prescription log or copies of actual prescriptions
- Medical records of previous treatment, if available, particularly treatment related to past suicide attempts

DOCUMENTING

Critical junctures for documentation:

- At first psychiatric assessment or admission
- With occurrence of any suicidal behavior or ideation
- Whenever there is any noteworthy clinical change
- For inpatients, before increasing privileges or giving passes and before discharge

DOCUMENTING

Sample suicide risk assessment note

- Suicide risk factors identified and weighed (low, moderate, high)
    - *Identify modifiable factors*
- Protective factors identified and weighed (low, moderate, high)
- Overall assessment rated (low, moderate, high, or range)
- Treatment and management intervention informed by the assessment
- Effectiveness of interventions evaluated

(Simon and Hales, 2006)

CAREFUL DOCUMENTATION

Remember:

- There’s no such thing as a perfect record
- Defense attorneys can work with adequate records
- Defense attorneys cannot work with no records or altered records

CAREFUL DOCUMENTATION

Professional Judgment – Bottom Line:

- By articulating the basis for medical decisions in the record, the psychiatrist's professional medical judgment will be clear and available to defend the psychiatrist against allegations of malpractice.

DOCUMENTATION & PROFESSIONAL JUDGMENT – GENERAL PRINCIPLES

- Do not let attorneys and their experts make up their own story about your treatment
  - Document your decision-making
- A physician who chooses one therapeutic approach from a number of reasonable approaches should not be held liable solely because it appears after-the-fact that a different reasonable approach might have been more beneficial
- Courts defer to the treating physician – as long as there is something to base that deference on
  - Contemporaneous documentation of treatment

PSYCHOPHARMACOLOGY

COMMON ALLEGATIONS

Failure to:

- Perform adequate history and physical
- Properly prescribe
- Properly diagnose
- Obtain consultation or make referral
- Adequately inform of side effects
- Obtain informed consent

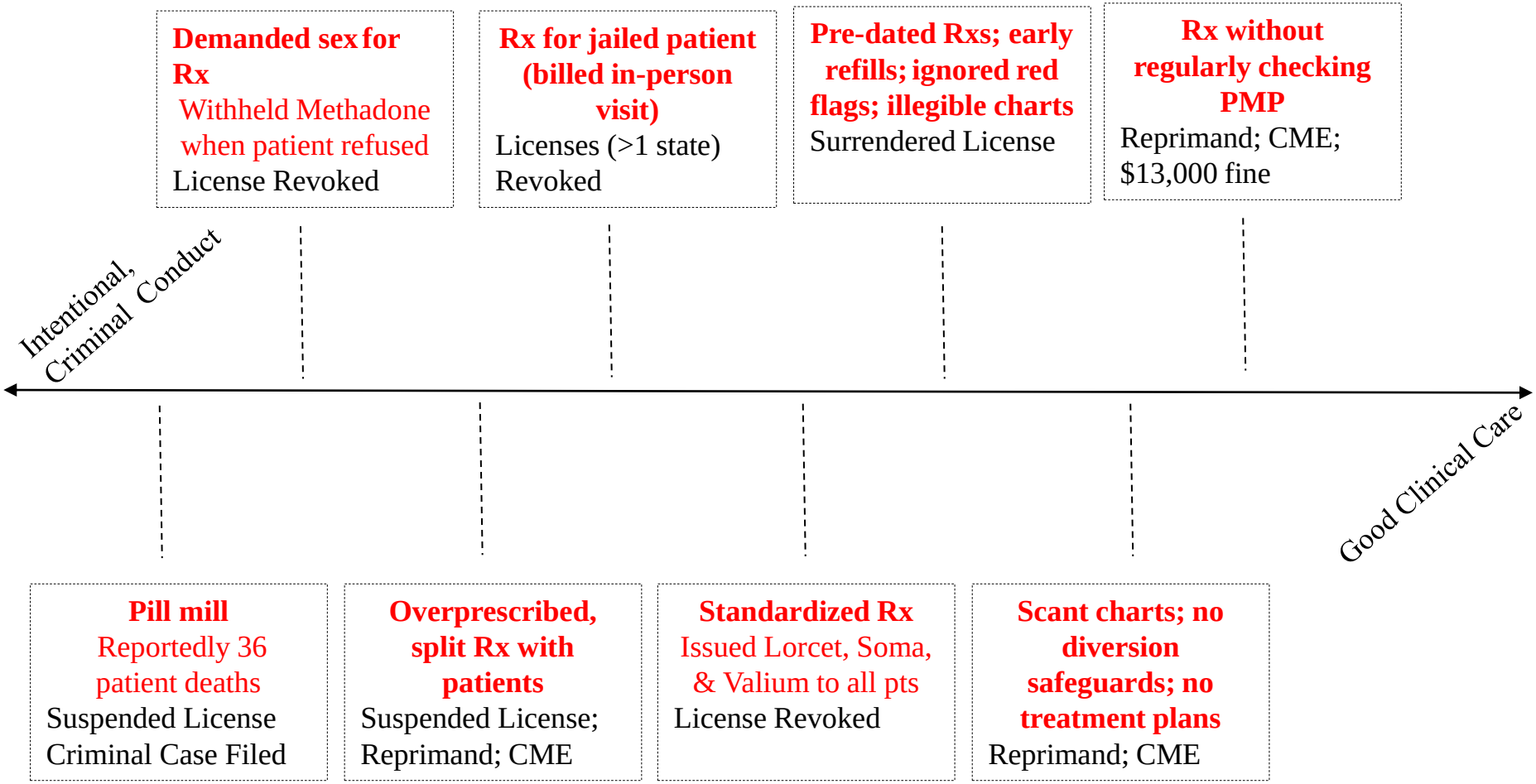
COMMON ALLEGATIONS

Failure to:

- Appropriately order and monitor lab testing
- Recognize and appropriately respond to adverse drug reactions
- Communicate with other providers
- Adequately screen for contraindications
- Access and review PMP data

COMMON PITFALLS

- Lithium levels
- RFT
- Depakote levels
- LFT
- Screening for metabolic disorders
- AIMS testing
- Checking the PMP database


Demanded sex for Rx
Withheld Methadone when patient refused
License Revoked
Rx for jailed patient (billed in-person visit)
Licenses (>1 state) Revoked
Pre-dated Rxs; early refills; ignored red flags; illegible charts
Surrendered License
Rx without regularly checking PMP
Reprimand; CME; $13,000 fine
Intentional, Criminal Conduct
Good Clinical Care
Pill mill
Reportedly 36 patient deaths
Suspended License
Criminal Case Filed
Overprescribed, split Rx with patients
Suspended License; Reprimand; CME
Standardized Rx
Issued Lorcet, Soma, & Valium to all pts
License Revoked
Scant charts; no diversion safeguards; no treatment plans
Reprimand; CME

Department of Justice

U.S. Attorney's Office

Central District of California

SHARE

FOR IMMEDIATE RELEASE

Thursday, August 3, 2017

Operators of Bogus Medical Clinics Charged in Conspiracy to Divert Massive Amounts of Prescription Narcotics to the Black Market

Glendale Defense Attorney and Others Involved in Scheme Allegedly Obstructed Justice by Creating Fake Medical Records to Justify Fraudulent Prescriptions

LOS ANGELES – The operators of seven sham medical clinics were among 12 defendants taken into custody this morning on federal drug trafficking charges that allege they diverted at least 2 million prescription pills – including oxycodone and other addictive and dangerous narcotics – to the black market.

Two indictmen
conspiracy profited f
through a series of cl
prescriptions alleged
sold on the street.

Those arrested
Mike," who is charge
hired corrupt doctor
exchange for kickbac

"The two indictments charge 14 defendants who allegedly participated in an elaborate scheme they mistakenly hoped would conceal a high-volume drug trafficking operation," said Acting United States Attorney Sandra R. Brown. "In addition to generating illicit profits, this scheme helped drive the prescription drug epidemic that is causing so much harm across our nation."

In a recorded conversation described in court documents, Matosyan discussed how one doctor was paid "for sitting at home," while thousands of narcotic pills were prescribed in that doctor's name and Medicare was billed more than $500,000 for purported patient care.

The conspirators also allegedly stole the identities of doctors who refused to participate in the scheme. In an intercepted telephone conversation described in court documents, Matosyan offered a doctor a deal to "sit home making $20,000 a month doing nothing." When the doctor refused the offer, the conspirators nevertheless created prescription pads in the doctor's name and allegedly began selling fraudulent prescriptions for oxycodone without the doctor's knowledge or consent.

www.justice.gov/usao-cdca/pr/operators-bogus-medical-clinics-charged-conspiracy-divert-massive-amounts-prescription
Accessed August 4, 2017

DEA REGULATIONS

Ex: 21 CFR 1306.04(A):

"A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose…by an individual practitioner…acting in the usual course of his professional practice"

PENNSYLVANIA CODE

49 Pa. Code § 16.92. Prescribing, administering and dispensing.

§ 16.92. Prescribing, administering and dispensing.

(a) For purposes of this section, ‘‘drug’’ includes the following:

(1) Controlled substances under The Controlled Substance, Drug, Device and Cosmetic Act (35 P. S. § § 780-101—780-144) or substances that are controlled substances under Federal law.

(2) Carisoprodol or agents in which carisoprodol is an active ingredient.

(3) Butalbital or agents in which butalbital is an active ingredient.

(4) Tramadol hydrochloride or agents in which tramadol hydrochloride is an active ingredient.

(b) When prescribing, administering or dispensing drugs regulated under this section, a person licensed to practice medicine and surgery in this Commonwealth or otherwise licensed or regulated by the Board shall carry out, or cause to be carried out, the following minimum standards:

(1) *Initial medical history and physical examination.* An initial medical history shall be taken and an initial physical examination shall be conducted unless emergency circumstances justify otherwise. Medical history and physical examination information recorded by another licensed health care provider may be considered if the medical history was taken and the physical examination was conducted within the immediately preceding 30 days. The physical examination shall include an objective evaluation of the heart, lungs, blood pressure and body functions that relate to the patient’s specific complaint.

(2) *Reevaluations.* Reevaluations of the patient’s condition and efficacy of the drug therapy shall be made consistent with the condition diagnosed, the drug or drugs involved, expected results and possible side effects.

(3) *Patient counseling.* The patient shall be counseled regarding the condition diagnosed and the drug prescribed, administered or dispensed. Unless the patient is in an inpatient care setting, the patient shall be specifically counseled about dosage levels, instructions for use, frequency and duration of use and possible side effects.

(4) *Medical records.* Accurate and complete medical records must document the evaluation and care received by patients.

United States Department of Justice
Drug Enforcement Administration
Office of Diversion Control

Practitioner's Manual

An Informational Outline of the Controlled Substances Act

http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf

Injury Prevention & Control: Opioid Overdose

CDC Guideline for Prescribing Opioids for Chronic Pain

Improving the way opioids are prescribed through clinical practice guidelines can ensure patients have access to safer, more effective chronic pain treatment while reducing the number of people who misuse, abuse, or overdose from these drugs.

CDC developed and published the CDC Guideline for Prescribing Opioids for Chronic Pain to provide recommendations for the prescribing of opioid pain medication for patients 18 and older in primary care settings. Recommendations focus on the use of opioids in treating chronic pain (pain lasting longer than 3 months or past the time of normal tissue healing) outside of active cancer treatment, palliative care, and end-of-life care.

What do you need to know?

Patients
Information and resources for patients

Health Care Providers
Overview of the guideline for providers

Resources
Fact sheets, clinical tools, and other materials related to the guideline

Clinical practices addressed in the guideline

- Determining when to initiate or continue opioids for chronic pain outside of active cancer treatment, palliative care, and end-of-life care
- Opioid selection, dosage, duration, follow-up, and discontinuation
- Assessing risk and addressing harms of opioid use

Learn More

FSMB: MODEL POLICY FOR THE USE OF OPIOID ANALGESICS IN THE TREATMENT OF CHRONIC PAIN

UNIVERAL PRECAUTIONS – SUMMARIZED:

1) Make a diagnosis with an appropriate differential.
2) Conduct a patient assessment, including risk for substance use disorders.
3) Discuss the proposed treatment plan with the patient and obtain informed consent.
4) Have a written treatment agreement that sets forth the expectations and obligations of both the patient and the treating physician.
5) Initiate an appropriate trial of opioid therapy, with or without adjunctive medications.

FSMB: MODEL POLICY FOR THE USE OF OPIOID ANALGESICS IN THE TREATMENT OF CHRONIC PAIN

UNIVERSAL PRECAUTIONS – CONTINUED

6) Perform regular assessments of patient and function.
7) Reassess the patient's pain score and level of function.
8) Regularly evaluate the patient in terms of the "5 A's": Analgesia, Activity, Adverse effects, Aberrant behaviors, and Affect.
9) Periodically review the pain diagnosis and any comorbid conditions, including substance use disorders, and adjust the treatment regimen accordingly.
10) Keep careful and complete records of the initial evaluation and each follow-up visit.

THE ISSUE:
MISUSE OF CONTROLLED SUBSTANCES

- Abuse
- Addiction
- Overdose
- Diversion

Morbidity and Mortality Weekly Report (*MMWR*)

Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015

Weekly / July 7, 2017 / 66(26);697–704

Gery P. Guy Jr., PhD[1]; Kun Zhang, PhD[1]; Michele K. Bohm, MPH[1]; Jan Losby, PhD[1]; Brian Lewis[2]; Randall Young, MA[2]; Louise B. Murphy, PhD[3]; Deborah Dowell, MD[1] (View author affiliations)

Abstract

Background: Prescription opioid–related overdose deaths increased sharply during 1999–2010 in the United States in parallel with increased opioid prescribing. CDC assessed changes in national-level and county-level opioid prescribing during 2006–2015.

Methods: CDC analyzed retail prescription data from QuintilesIMS to assess opioid prescribing in the United States from 2006 to 2015, including rates, amounts, dosages, and durations prescribed. CDC examined county-level prescribing patterns in 2010 and 2015.

Results: The amount of opioids prescribed in the United States peaked at 782 morphine milligram equivalents (MME) per capita in 2010 and then decreased to 640 MME per capita in 2015. Despite significant decreases, the amount of opioids prescribed in 2015 remained approximately three

Key Points

- The amount of opioids prescribed in the United States peaked in 2010 and then decreased each year through 2015. Despite reductions, the amount of opioids prescribed remains approximately three

THE RESPONSE: REGULATION

- Federal
- State

FEDERAL VERSUS STATE

- DEA works closely with state licensing boards and state local law enforcement
- Majority of investigations of controlled substance laws are done by state authorities
- DEA will also conduct investigations of federal law

FEDERAL

DEA PROBLEM AREAS:

1) Failure to recognize doctor shoppers
   - Red Flags
     - Symptom incompatible with reported injury
     - Visit physician some distance from home
     - History of problems with no medical records
     - Multiple accidents
     - Insist on drug of choice
     - Loss of prescription or medication
     - Fails to provide or go for testing
     - Takes more meds than directed
     - Requests meds early
     - Meds from multiple physicians
     - Prescriptions filled at multiple pharmacies

www.acponline.org/about_acp/chapters/az/rivera-armando.pdf

FEDERAL

DEA PROBLEM AREAS:

2) Diversion
   - Methods
     - Practitioners / Pharmacists
     - Employee pilferage
     - Pharmacy theft
     - Patients / Drug Seekers
     - Medicine Cabinet / obituaries
     - Internet
     - Pain Clinics

www.mbc.ca.gov/board/meetings/materials_2013_02_21_prescribing-2.pdf

FEDERAL

(*CONTINUED*)

- Possible indicators
  - Inordinately large quantity of controlled substances was prescribed
  - Large numbers of prescriptions were issued
  - No physical exam
  - Physician warned patient to fill prescriptions at different pharmacies
  - Physician issued prescriptions to patient known to be delivering drugs to others
  - Physician prescribed controlled substances at intervals inconsistent with legitimate medical treatment
  - Physician used street slang rather than medical terminology for drugs prescribed
  - No logical relationship between drugs prescribed and treatment of alleged condition

www.acponline.org/about_acp/chapters/az/rivera-armando.pdf

FEDERAL

DEA PROBLEM AREAS:

3) Excessive / Unauthorized Prescribing
4) Internet Prescribing

www.acponline.org/about_acp/chapters/az/rivera-armando.pdf

COLLECT INFORMATION

- Patient
- Medications
- Treatment / standard of care
- Abuse / diversion

COLLECT INFORMATION – ABOUT THE PATIENT

- History
- Prior records
- Previous psychiatrist
- Other clinicians
- Family
- PMP

COLLECT INFORMATION – ASSESSMENT AND MONITORING

- Conduct thorough patient examination, interview, and assessment
- Consider standardized assessment and documentation tool
  - Especially for pain

COLLECT INFORMATION – ABOUT THE MEDICATIONS

- Label
  - Know the label
  - Can change
    - FDA's MedWatch: www.fda.gov/Safety/MedWatch/default.htm

COLLECT INFORMATION – ABOUT TREATMENT / STANDARD OF CARE

- Medication-specific
  - Ex: opioids
- Patient-specific
  - Ex: C&A
- Expectations of regulators
  - State
  - Federal

COLLECT INFORMATION – ABOUT ABUSE

MODUS OPERANDI / SCAMS USED

- From the MO Task Force:
  - Obese person scam
  - Grandparent scam
  - Pain while traveling scam
  - Hyperactive child scam
  - Forged or stolen records scam

COLLECT INFORMATION – ABOUT ABUSE

MODUS OPERANDI / SCAMS USED

- From the MO Task Force (Continued):
  - Help me, I'm an addict scam
  - Police report scam
  - Friend in doctor's office scam
  - Asleep at wheel scam
  - Aggravated stump scam

http://health.mo.gov/safety/bndd/doc/PreventingPrescriptionFraud.doc

COMMUNICATION WITH PATIENTS

Educate the patient on issues such as:

- Restrictions (driving, diet, activity, etc.) associated with the medication
- Monitoring, such as blood work, that is needed
- Purpose, dose, and frequency of the medication
- How to identify side effects, and what to do if patient experiences
- Ensuring patient's other physicians are aware of new prescriptions

COMMUNICATE – INFORMED CONSENT

Standard Elements:

- Nature of proposed medication
- Risks and benefits of proposed medication
  - Including potential for tolerance, dependence, addiction, overdose
- Alternatives to proposed medication
- Risks and benefits of alternative treatments
- Risks and benefits of doing nothing

Plus:

- Prescribing policies
- Reasons for which medication may be changed or stopped

COMMUNICATE – INFORMED CONSENT

"MATERIAL RISK"

- Disclose risk if SEVERE, even if infrequent
- Disclose risk if FREQUENT, even if not severe
- FDA medication guides
- Disclose possible driving impairment
- Golden Rule

COMMUNICATE – INFORMED CONSENT

Medication Guides

- FDA
  - www.fda.gov/drugs/drugsafety/ucm085729.htm
- AACAP / ParentsMedGuide - ADHD
  - www.aacap.org/App_Themes/AACAP/Docs/resource_centers/adhd/adhd_parents_medication_guide_201305.pdf

FDA's Patient Counseling Document for Opioids

- www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm361110.pdf

COMMUNICATION WITH PATIENTS

Communicate to obtain informed consent:

- Reminders if you choose to use medication information sheets:
  - You are responsible for tailoring them to meet your patient's needs and for ensuring the information is up-to-date
  - Be sure to document in the record that the medication information sheet was reviewed with the patient and the patient was provided a copy

COMMUNICATION WITH PATIENTS

Communicate to obtain informed consent *(continued)*:

- Remember that informed consent is an ongoing communication process
- Know who has decision-making authority - obtain and retain proof of that authority
- Understand that communication is crucial to your patients' understanding of the treatment plan
- Document the informed consent process

COMMUNICATION WITH PATIENTS

Communicate to obtain informed consent *(continued)*:

- If you are prescribing off-label, discuss off-label nature of the use with the patient
  - FDA position
  - All off-label prescribing is NOT the same in terms of medical malpractice risk

COMMUNICATE – TREATMENT AGREEMENT

- Can Cover:
  - Intended benefits of using controlled substances
  - Risks of the treatment – tolerance, dependence, abuse addiction
  - Prescription management – security of meds

COMMUNICATE – TREATMENT AGREEMENT

- Can Cover (*Continued*):
  - Office policies
    - Only one prescriber
    - Only one pharmacy
    - Not replacing lost or stolen prescriptions
    - Prohibiting dose or frequency increased by patient
    - Use of PMP
    - Random pill counts
    - Random urine screening
  - Termination for
    - Failure to adhere to treatment plan
    - Aberrant Behavior

COMMUNICATE – WITH OTHERS

- Other providers:
  - Covering
  - PCP, specialists
  - Consultants
- Family
  - Remember: safety = exception to confidentiality

CAREFULLY DOCUMENT

Generally:

- Medication log
- Evaluation
- Medical indication for prescription
- Treatment plan
  - Initial
  - Updated
- Treatment agreement, if any
  - Subsequent discussions about agreement

CAREFULLY DOCUMENT

Generally (*Continued*):

- Informed consent
  - Patient Education Materials
- Ongoing assessment
  - Adherence to treatment plan
  - Medication monitoring
  - Aberrant behavior
- Referral / consultation, if necessary
- Basis for clinical decision-making

CAREFULLY DOCUMENT

Consider:

- Treatment agreement
- Standardized assessment form

DRIVING: LIABILITY TO THIRD PARTIES

Two lines of cases imposing liability:

1) Controlled substance (usually methadone) was ADMINISTERED despite risks that were known or should have been known

2) Controlled substance was PRESCRIBED without warning patient of known side effects that could impair driving

TELEPSYCHIATRY & MEDICAL MARIJUANA

- Some states prohibit using telemedicine to conduct the examination required to certify for medical marijuana
- The face-to-face examination requirement poses a challenge when establishing a treatment relationship via telepsychiatry

TELEPSYCHIATRY

ICNS INNOVATIONS IN CLINICAL NEUROSCIENCE

Peer-reviewed,evidence-based information for clinicians and researchers in the field of neurotherapeutics

Telepsychiatry and Risk Management

ICN Online Editor | September 30, 2011 | 0 Comments

by Charles D. Cash, JD, LLM

Mr. Cash is Senior Risk Manager for Professional Risk Management Services, Inc., Arlington, Virginia.

Innov Clin Neurosci. 2011;8(9):26–30

Question

I am thinking about incorporating some form of telemedicine into my practice. I hope to expand my practice and be able to treat a few of my patients who live quite a distance from my office. A few of my colleagues have done this using their office desktop computers and software that allow high-quality video calling over the internet. Another colleague practices telemedicine through the hospital where he works. What do I need to consider before I take on a telemedicine endeavor?

Answer

As the use of technology in medicine rapidly expands, psychiatrists inevitably will consider how some of those technologies might be applied to their practices. Telemedicine is the use of technology to facilitate clinical care at a distance and includes, among many fields of telemedicine, telepsychiatry. Telemedicine technologies include, but are not limited to, telephone, e-mail, and real-time videoconferencing.

Telepsychiatry, if done well, can benefit patients. It also presents significant risks for the unwary. The following issues should be thoughtfully and carefully considered before adopting telepsychiatry into your practice.

Preliminary considerations

The first step in any telepsychiatry endeavor is to define what you want to do and how you will do it. This is essentially business planning; determining what services will be offered, to whom they will be offered, and the technology used to offer them. The article entit
provides a thorough discus

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.

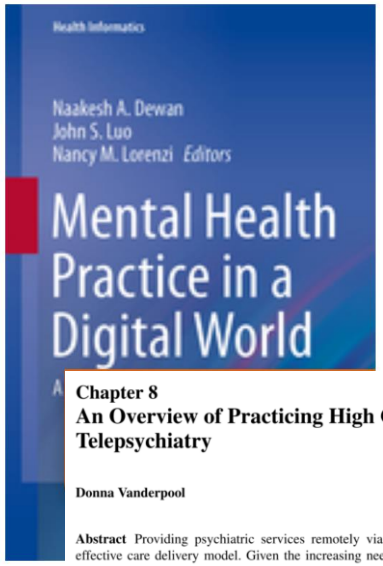
The technology for remote treatment is advancing rapidly. The regulatory environment in which psychiatrists practice telepsychiatry is also evolving but at a much slower pace than the technology. As introduced in this journal years ago by my colleague Charles D. Cash in his article, "Telepsychiatry and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

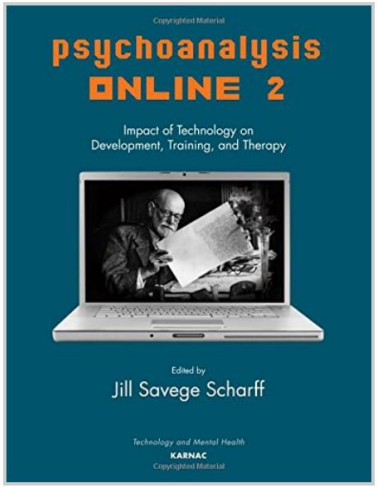
1. If the patient is in a different state than the provider, and the provider is not licensed in the patient's state, the patient's state licensing board should be contacted to determine whether licensure in the patient's state is required. While almost all states require some type of licensure or registration, 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



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

Coronavirus FAQs

UPDATED: September 17, 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 INQUIRED 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
- State Guidelines for Re-Opening a Medical Office
- Telepsychiatry Checklist (Updated 9/2/20)
- Preparing For What's Next - To Do List
- Telepsychiatry and COVID-19: What We Do and Do Not Know On-Demand Tutorial

NEW/UPDATED FAQS
PATIENT CARE ISSUES
OFFICE ISSUES
REMOTE TREATMENT - TELEPHONE
TELEPSYCHIATRY - CLINICAL ISSUES
TELEPSYCHIATRY - ADMINISTRATIVE ISSUES
PRESCRIBING CONTROLLED SUBSTANCES
HIPAA AND 42 CFR PART 2
COMPUTER SECURITY/PHISHING
YOUR UNAVAILABILITY
ETHICS
RESOURCES
OLDER FAQs

www.prms.com/faq

TAKE AWAY POINT #1

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

TAKE AWAY POINT #2

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.

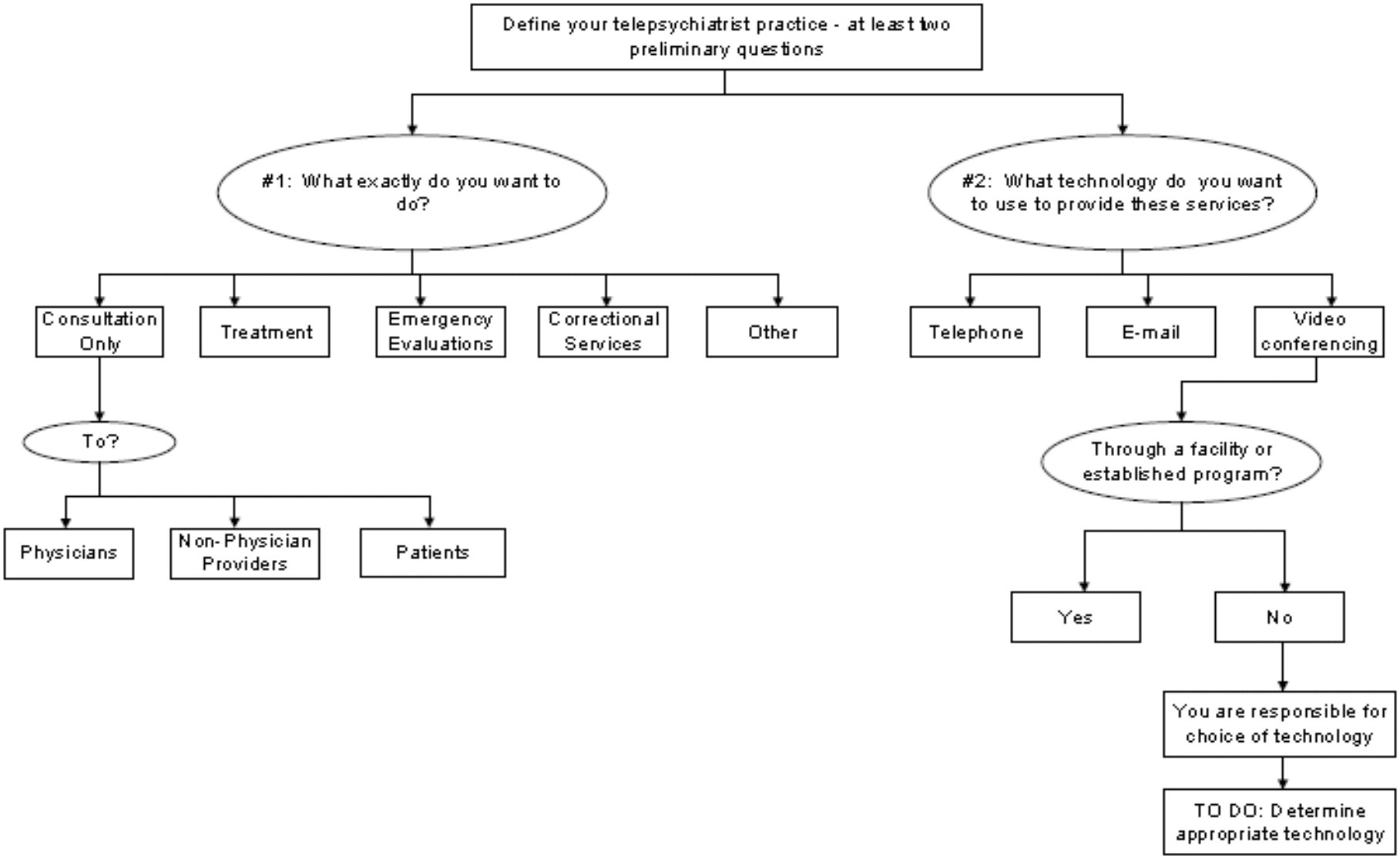
TAKE AWAY POINT #3

Research/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
- Prescribing
- Other requirements – CME, e-prescribing, renewal
- Telehealth regulations

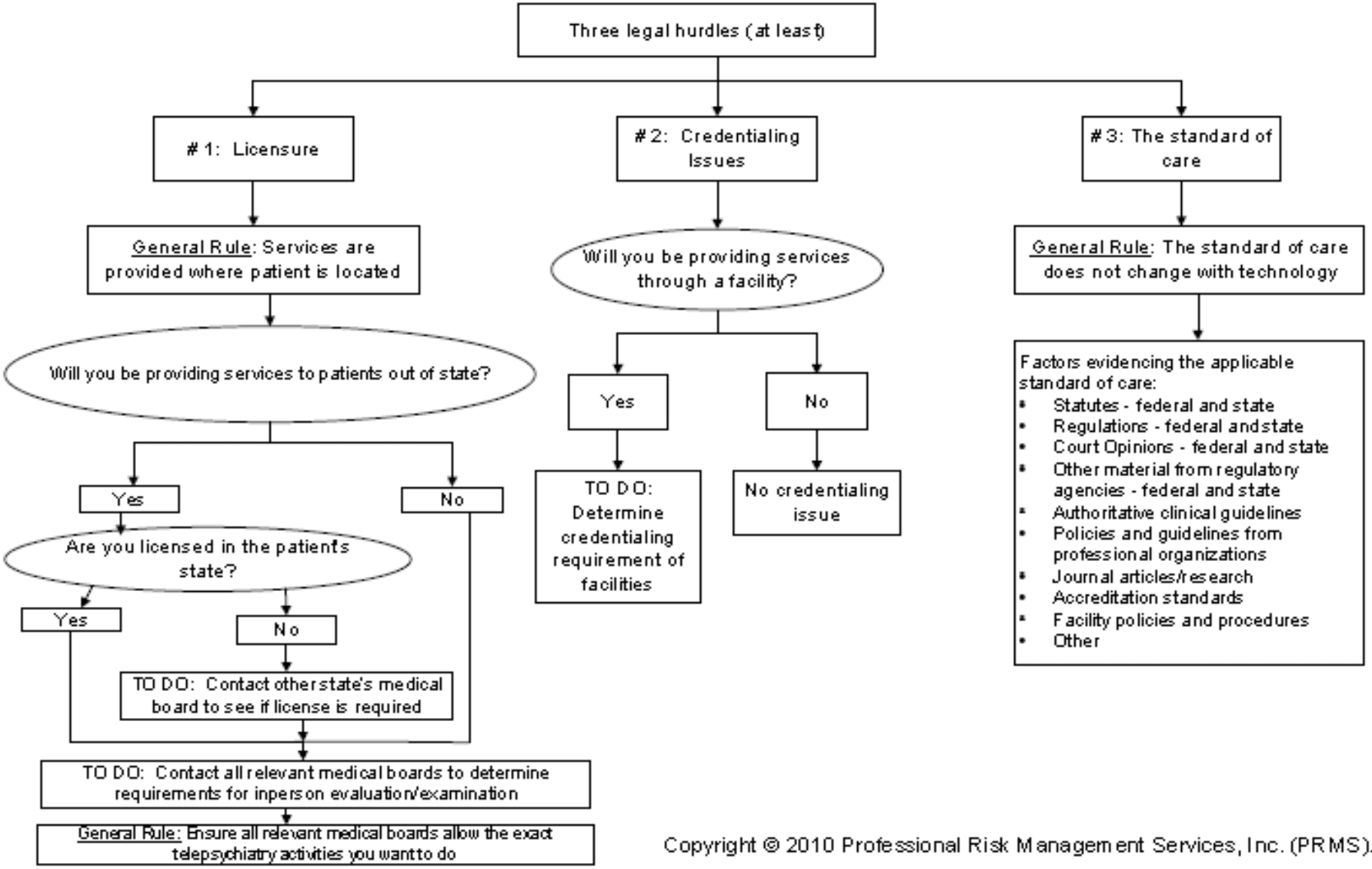
TELEPSYCHIATRY

PRELIMINARY DETERMINATIONS



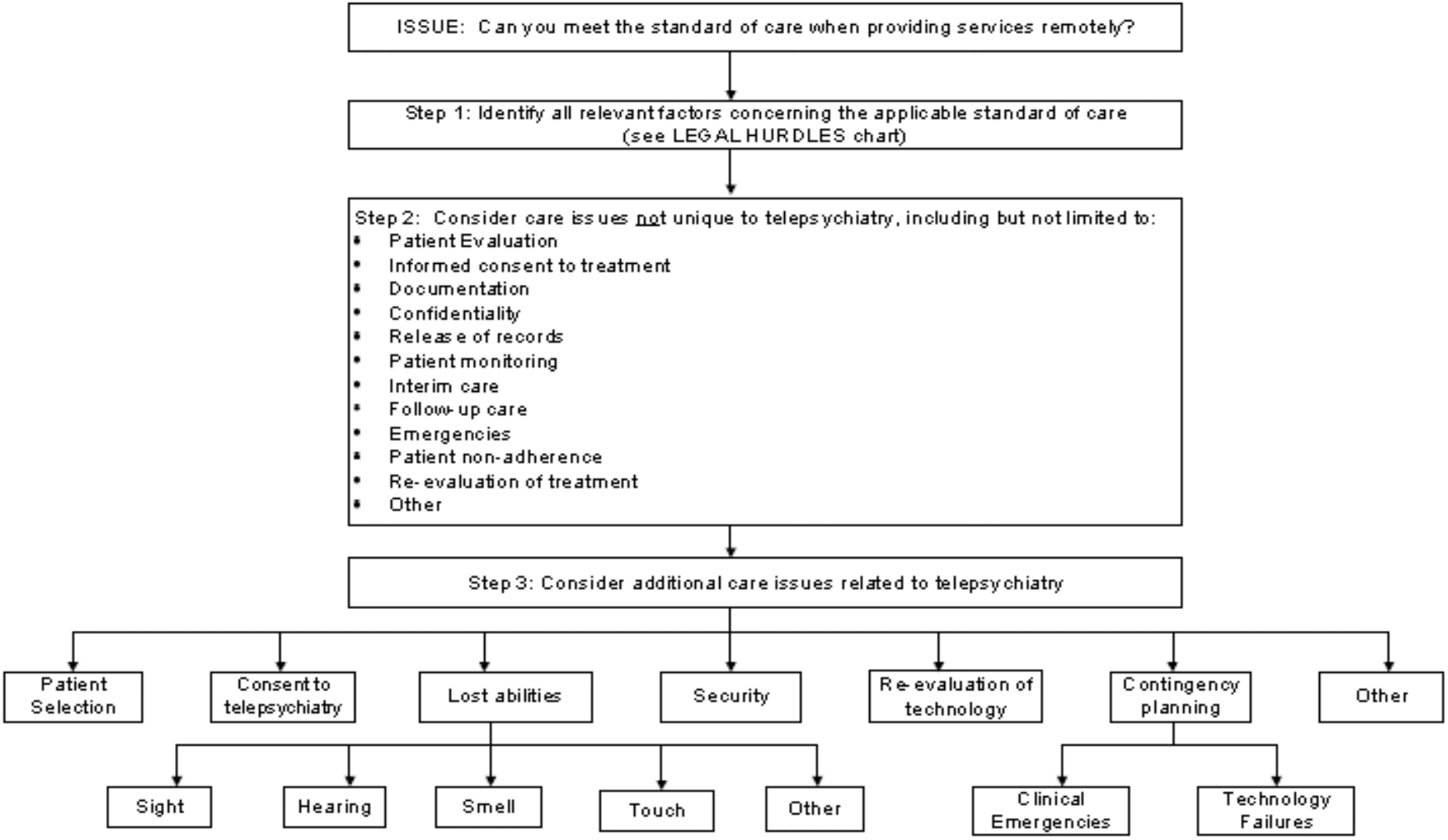
TELEPSYCHIATRY

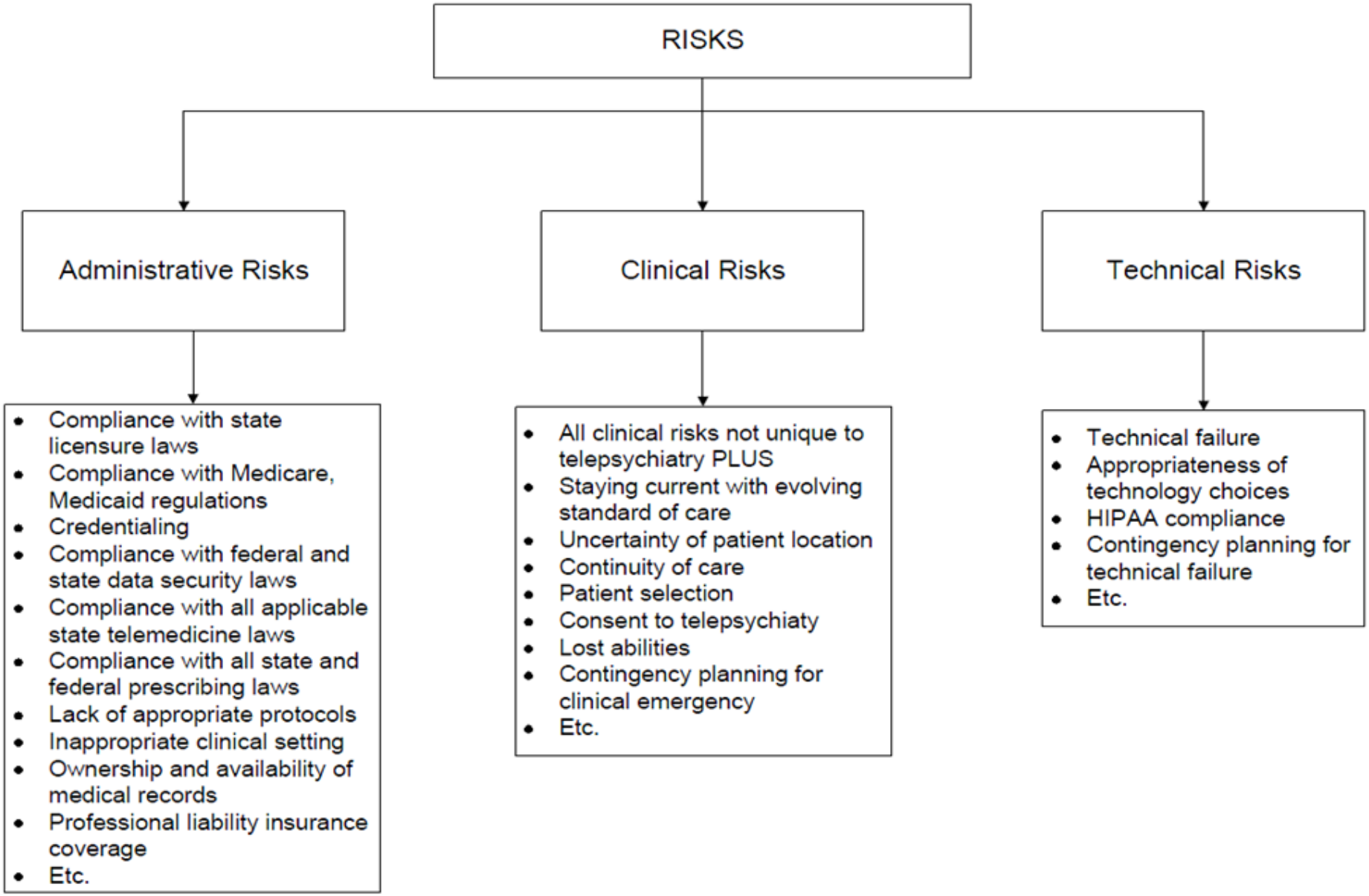
LEGAL HURDLES

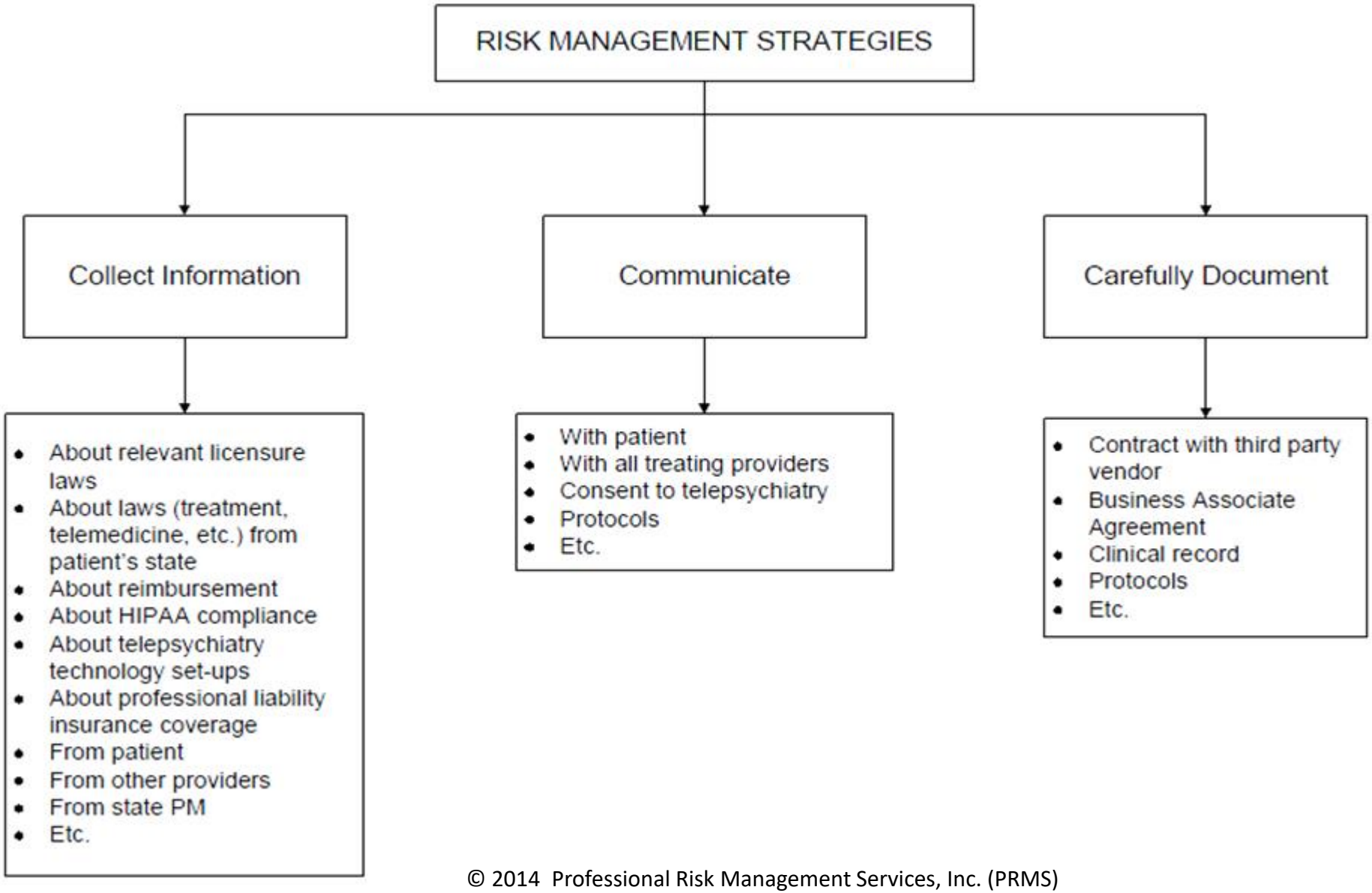


TELEPSYCHIATRY

CLINICAL HURDLES







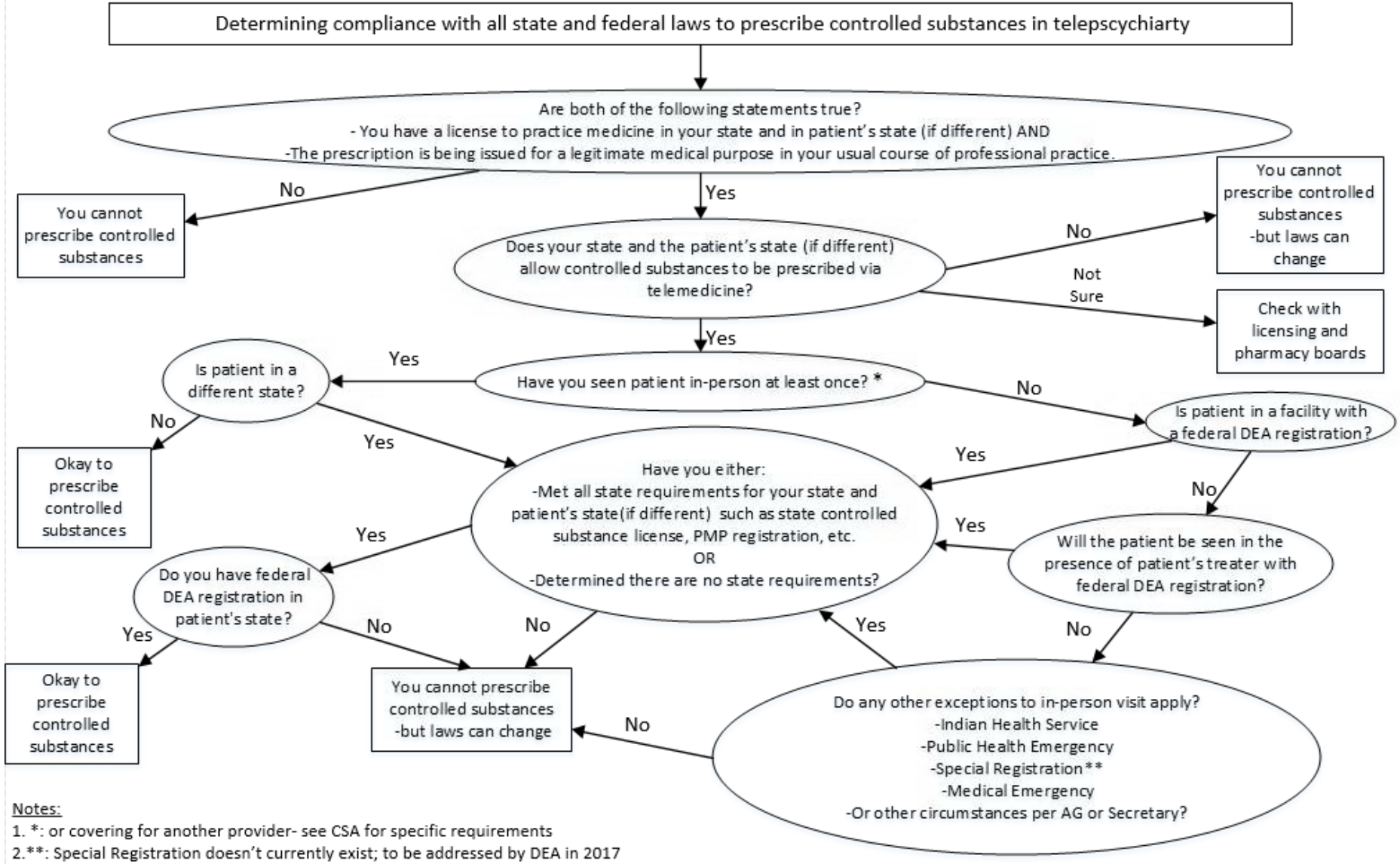
TO PRESCRIBE VIA TELEMEDICINE

- Ensure compliance with all state and federal laws, including:
  - State law – some states prohibit
  - Federal Controlled Substance Act
    - Including the Ryan Haight Act amendment
  - Federal DEA registration requirements
    - In each state you prescribe in
  - State equivalent of federal DEA registration, if applicable

TELEPSYCHIATRY-
FACE-TO-FACE EVALUATION

- Federal law (CSA as amended by the RHA)
- Some boards say in-person exam is not required
- Some boards say it depends
  - On the patient's condition

Determining compliance with all state and federal laws to prescribe controlled substances in telepscychiarty



Notes:

1. *: or covering for another provider- see CSA for specific requirements
2. **: Special Registration doesn't currently exist; to be addressed by DEA in 2017
3. This is a risk management resource- it is not legal advice.
4. There can always be exceptions to these rules, especially if practicing within VA or IHS.
5. You should check with licensing boards in your state, and patient state's (if different) for specific requirements and prohibitions.

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.*

QUESTIONS?