PROFESSIONAL LIABILITY EXPOSURES IN CLINICAL PRACTICE AND RISK MANAGEMENT

Wellspan Philhaven

November 3 & 10, 2020

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Associate Director of Risk Management

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

RECAP: THE STATE OF PROFESSIONAL LIABILITY

Behavioral health is a low-risk calling

Greatest Professional Liability Exposure

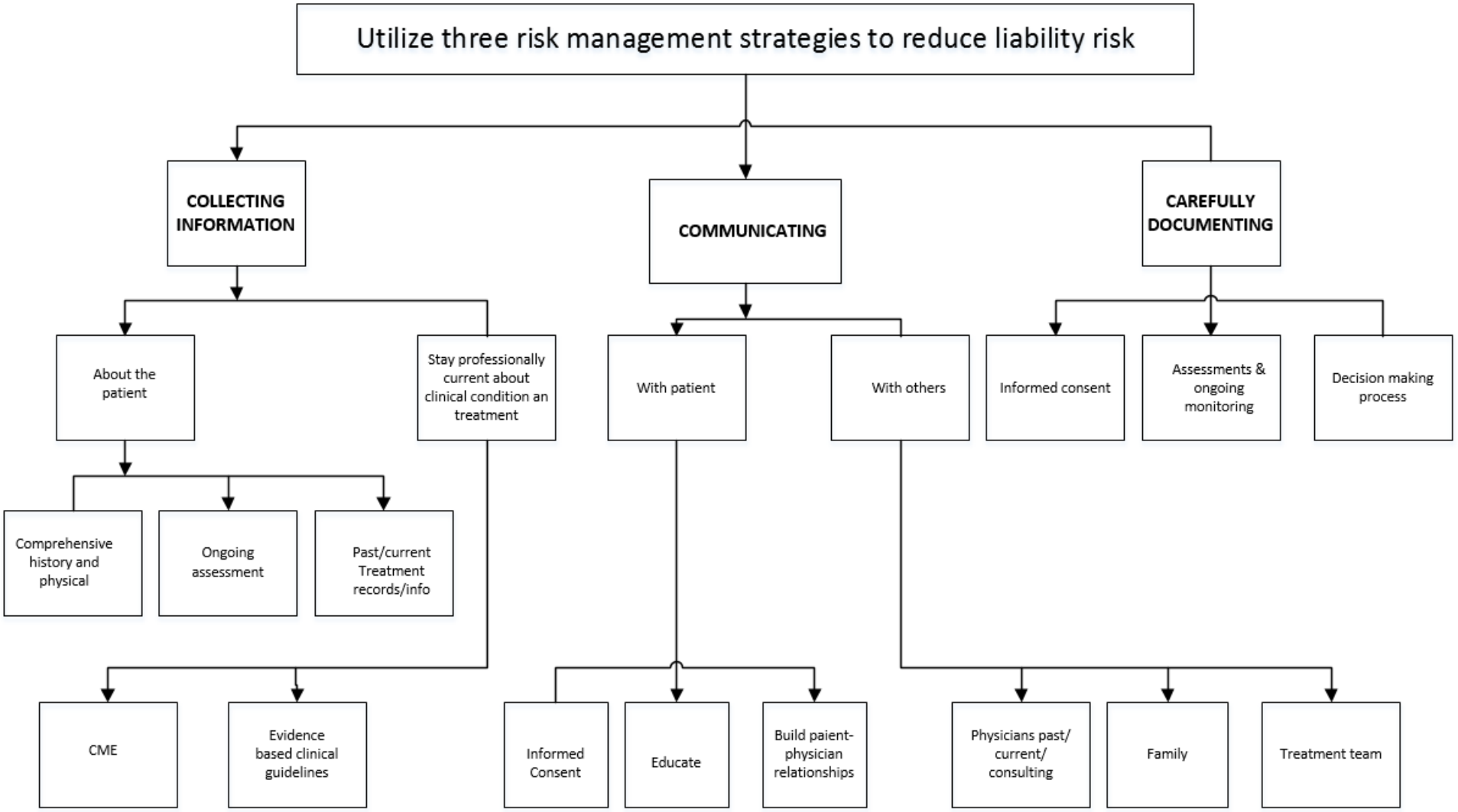
- Patient suicide / attempted suicide
- Psychopharmacology

Administrative actions are a significant exposure

Elements of a malpractice suit

- Duty
- Breach
- Causation
- Damages

3 Cs of RISK MANAGEMENT



RECAP: RISK REDUCTION RECIPE

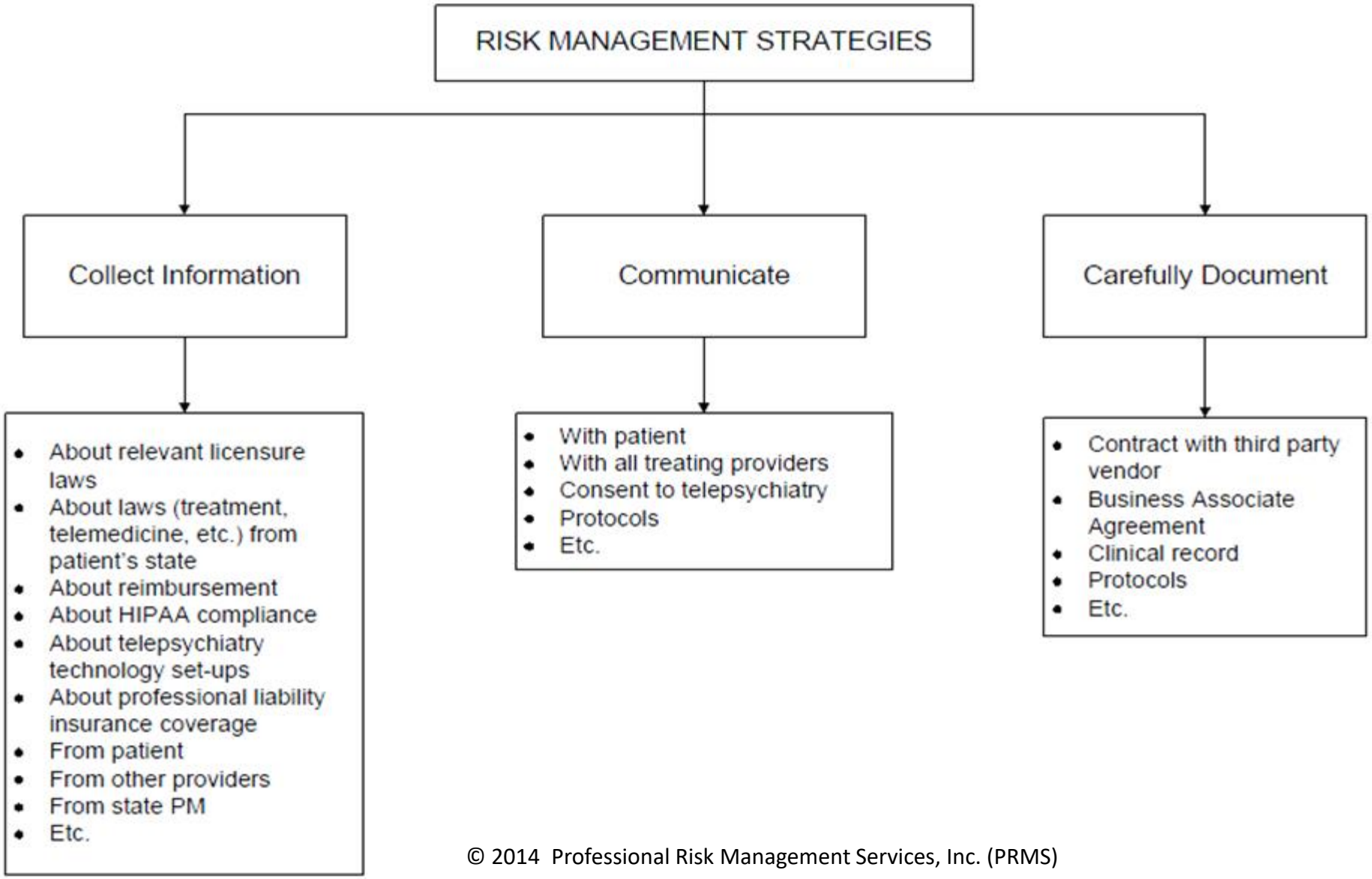
Suicide

- Assess
- Assess
- Assess
- Consider a formal assessment tool

Medications

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

RECAP: TELEHEALTH



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

COLLABORATION & LIABILITY FOR THE ACTS OF OTHERS

THEORIES OF NEGLIGENCE

Vicarious Liability/Respondeat Superior

- Employee acting in course of his/her employment
- No negligence on part of MD required

Negligent Supervision

- Look to state laws regarding supervision of NPPs

Negligent Hiring/Retention

- MD failed to conduct sufficient investigation prior to hiring

Lack of Informed Consent

- Patient believed he/she was being treated by an MD

TREATMENT DELIVERY ARRANGEMENTS

Collaboration: mutually shared responsibility for patient's care in accordance with the qualifications and limitations of each professional's discipline and abilities.

- **Split Treatment:** one psychiatrist (or physician) provides medication management and another psychiatrist provides psychotherapy
  - May be interpreted as supervision if therapist is non-physician provider
  - No change in psychiatrist's duty to the patient – always liable for ensuring that patient receives appropriate care

TREATMENT DELIVERY ARRANGEMENTS

Split Treatment – Risk Management Advice:

- Communication among all parties
- Collaboration agreement to clarify relationship
  - Clarify to patient the division of treatment responsibilities and that neither provider supervises the other, if that is the case
    - Example: who will the patient contact if he has a crisis?

TREATMENT DELIVERY ARRANGEMENTS

Supervision:

- Supervisor retains direct responsibility for patient care
- To minimize liability exposure
  - Ensure good communication
  - Tailor involvement to each situation based on
    - Patient's needs
    - Education and experience of supervisee
    - Type of treatment
- Supervisor and supervisee must be clear on
  - All applicable laws and regulations
  - Expectations of both parties

TREATMENT DELIVERY ARRANGEMENTS

Consultation:

- True consult – only opinion is provided
    - Requesting provider can accept or reject consultant's opinion and recommendations
- Consultant does not assume responsibility for patient's care
- Least liability exposure

TREATMENT DELIVERY ARRANGEMENTS

Office Sharing:

- Psychiatrists can be held liable for acts of another with whom he/she merely shares office space
- Patients' perceptions are key

TREATMENT DELIVERY ARRANGEMENTS

Office Sharing – To Minimize Liability:

- Have business attorney review practice arrangement
- Office mates
  - Make sure no serious complaints have been filed
  - Make sure they have limits of professional liability coverage at least equal to yours
- Avoid appearance of any control or supervision of office mates
- Keep all records separate from those of office mates

TREATMENT DELIVERY ARRANGEMENTS

Office Sharing – To Minimize Liability: *(continued)*

- Eliminate objective indicators of association with office mates, such as:
  - Shared letterhead
  - Shared signs
  - Shared telephone numbers, etc.
- Post and provide to all patients a notice
  - Independent practitioners
  - No partnership
  - No control or supervision over the others

TREATMENT DELIVERY ARRANGEMENTS

Office Sharing – To Minimize Liability: *(continued)*

- Periodically check to confirm that written procedures are being followed
- Understand the ethical and legal issues related to fee-splitting when accepting/paying a percentage of fees collected for office space and administrative support

SUPPORT STAFF AND NON-PHYSICIAN PROVIDERS

Psychiatrists are held liable for the acts of employees, affiliates, and contractors.

NON-PHYSICIAN PROVIDERS (NPPs)

Physician Assistant

- Typically must be under the supervision of a physician

Nurse Practitioner

- Often can practice independently with a written collaborative practice agreement with MD

Psychologist

Social Worker

Others

MEDICAL BOARD COMPLAINTS

In addition to liability exposure, physicians may be subject to Board complaints for:

- Allowing unlicensed person to perform activity requiring license
- Improper delegation of duties
- Improper supervision

MINIMIZING EXPOSURE

Initial Considerations

- What are your practice needs?
- Familiarize yourself with state laws regarding NPPs
  - Scope of practice
  - Supervision requirements
- What category of NPP best suits your practice?
- Who will supervise?
- Does supervising physicians have time and temperament to do so?

MINIMIZING EXPOSURE

Prior to hiring, verify credentials:

- Education
- Licensing status/Board complaints
- Certification
- CE hours
- Employment history
- Malpractice history
- Credit check
- Criminal background check

MINIMIZING EXPOSURE

Before NPP begins employment:

- Create written job description, practice protocols, and/or collaborative treatment agreement, as appropriate
  - Types of patients to be seen by NPP
  - When physician should be consulted
  - Prescriptive authority
  - Role of supervising physician
  - Availability of supervising physician and back up physician
  - Requirements for and frequency of chart review by physician
  - Frequency of skills review
  - Provisions for protocol review

MINIMIZING EXPOSURE

Patient Satisfaction

- Practice brochures/websites should introduce NPP and explain role in practice
- Receptionist should clearly state appointment is with NPP
- Correct patient who refers to NPP as “doctor”
- Patients who insist should be seen by MD

MINIMIZING EXPOSURE

Documentation

- Personnel files
  - Credential verification
    - What, when, to whom you spoke
  - Training/Protocol review
    - Dates, specific training

- Patient files
  - Annotate to explain role when reviewing
    - Reviewed by …
    - Under the supervision of …

CASE STUDY

Doe v. Guthrie Clinic, Ltd.

- Patient treated for STD
- Nurse texted patient's girlfriend
- Texts unrelated to treatment
- Patient complained, nurse fired
- No liability because conduct not within scope of employment

BUT……

- Entity could be liable if lacking adequate policies and procedures to safeguard PHI and training regarding policies and procedures

2014 U.S. App. LEXIS 1644

SUPPORT STAFF

Areas of exposure

- Only staff with appropriate training and professional credentials should provide clinical information or recommendations to patients
- If staff phone in prescriptions (other than for controlled substances), physician will be liable for any error
- Mishandling patient information
  - Failure to timely release records
  - Erroneous release of information
  - Inappropriately accessing PMP data

SUPPORT STAFF

Mitigating Risk

- Implement protocols and procedures
  - General office protocols and procedures
  - Confidentiality
    - Confidentiality agreements
    - Social media policy
  - Others
- Train and retrain staff
  - Document training efforts
- Revisit and revise protocols as necessary
  - Ensure all staff, even temporary employees, are adequately trained in and follow all office policies and procedures

SUPPORT STAFF

General policies and procedures to consider:

- Telephones, fax, e-mail, computers
- Securing laptops, PDAs, and backup media
- Responding to requests for patient information
- Prescription refills
- Patient complaints
- Confidentiality – Social media
- Billing & collections
- Tracking missed appointments, laboratory tests, consultations, and referrals

NON-ADHERENT PATIENTS

WHO ARE THEY?

The signs

- Missed appointments
- Labs
- Prescriptions
- Worsening symptoms/no improvement
- Risky behavior

WHO ARE THEY?

Digging deeper

- How are they taking meds?
- When?
- Doses missed?
- Side-effects
- Refills
- Appointments

BARRIERS TO ADHERENCE

- Health literacy
- Language
- Culture
- Hearing ability
- Poverty

NON-ADHERENCE & MEDICATION

- Anosognosia
- Multiple prescriptions
- Dosing confusion
- Difficulty taking
- Side-effects
- Addiction concerns
- Personality

NON-ADHERENCE & MEDICATION

- Stigma
- Slow results
- Cost
- Benefits not recognized
- Improvement = cure

FACILITATING ADHERENCE

- Bring all medications
- One pharmacy
- Report new meds
- Therapeutic alliance
  - Why used
  - Expectations
  - Patient's role
  - Factors affecting adherence
  - Role of meds in achieving goals

FACILITATING ADHERENCE

- Written instructions
- Medication flow sheet
- Simplify dosing
- Devices
- Generics
- Patient assistance programs
- Adjust interventions

GOING FORWARD

- Ramifications of non-adherence
  - Patient's condition
  - Your ability to treat
  - Family?
- Termination
- Document

ELECTRONIC HEALTH RECORDS

EHR DOCUMENTATION

- Garbage in – garbage out
- Concerns about safety
  - ECRI
  - Joint Commission
- Lack of narrative
- Issues with template use
  - Inaccuracies
  - CMS 3rd-party payers
  - Informed consent, etc.

EHR DOCUMENTATION

- Autopopulation
  - Previous visit
  - Previous patient
  - Entered by clinician or system?
- Copy & paste
  - Scrutiny by CMS
  - Perpetuation erroneous info
  - Who authored?

EHR DOCUMENTATION

- Appropriate billing
  - System may generate documents for highest code
  - Code must reflect medical necessity
- Too much information
  - Can’t find relevant data
  - Time consuming
  - Print out and check accuracy

September 24, 2012

American Hospital Association
Richard Umbdenstock
President and Chief Executive Officer
325 Seventh Street, N.W.
Washington, DC 20004

Federation of American Hospitals
Charles N. Kahn, III
President and Chief Executive Officer
750 9th Street, NW, Suite 600
Washington, DC 20001-4524

Association of Academic Health Centers
Steve Wartman
President and Chief Executive Officer
1400 Sixteenth Street, NW, Suite 720
Washington, DC 20036

Association of American Medical Colleges
Darrell G. Kirch, M.D.
President and Chief Executive Officer
2450 N Street, NW
Washington, DC 20037-1126

National Association of Public Hospitals and Health Systems
Bruce Siegel, MD, MPH
President and Chief Executive Officer
1301 Pennsylvania Avenue, NW
Suite 950
Washington DC 20004

Dear Chief Executive Officers:

As leaders in the health care system, our nation's hospitals have been at the forefront of adopting electronic health records for use in coordinating care, improving quality, reducing paperwork, and eliminating duplicative tests. Over 55 percent of hospitals have already qualified for incentive payments authorized by Congress to encourage health care providers to adopt and meaningfully use this technology. Used appropriately, electronic health records have the potential to save money and save lives.

However, there are troubling indications that some providers are using this technology to game the system, possibly to obtain payments to which they are not entitled. False documentation of care is not just bad patient care; it's illegal. These indications include potential "cloning" of medical records in order to inflate what providers get paid. There are also reports that some hospitals may be using electronic health records to facilitate "upcoding" of the intensity of care

or severity of patients' condition as a means to profit with no commensurate improvement in the quality of care.

This letter underscores our resolve to ensure payment accuracy and to prevent and prosecute health care fraud. A patient's care information must be verified individually to ensure accuracy: it cannot be cut and pasted from a different record of the patient, which risks medical errors as well as overpayments. The Centers for Medicare and Medicaid Services (CMS) is specifically reviewing billing through audits to identify and prevent improperly billing. Additionally, CMS is initiating more extensive medical reviews to ensure that providers are coding evaluation and management services accurately. This includes comparative billing reports that identify outlier facilities. CMS has the authority to address inappropriate increases in coding intensity in its payment rules, and CMS will consider future payment reductions as warranted.

We will not tolerate health care fraud. The President initiated in 2009 an unprecedented Cabinet-level effort to combat heath care fraud and protect the Medicare trust fund, and we take those responsibilities very seriously.

Law enforcement will take appropriate steps to pursue health care providers who misuse electronic health records to bill for services never provided. The Department of Justice, Department of Health and Human Services, the FBI, and other law enforcement agencies are monitoring these trends, and will take action where warranted. New tools provided by the health care law authorize CMS to stop Medicare payments upon suspicion of fraud and to mine data to detect it in the first place. These efforts have contributed to record-high collections and prosecutions. Prosecutions in 2011 were 75 percent higher than in 2008. That said, we will continue to escalate our efforts to prevent fraud and pursue it aggressively when it has occurred.

The nation's hospitals share our goal of a health system that offers high quality, affordable care. We thank you for your relentless work toward this goal which can be better achieved once all Americans have privacy-protected electronic health records. The health information technology incentive program promotes electronic health records that go beyond documentation and billing and towards meaningful use as a foundation for new payment and delivery models. The Affordable Care Act has accelerated the spread of such models like Accountable Care Organizations, patient-centered homes, and value-based purchasing which shift the incentives away from volume and towards value. As we phase-in electronic health records, though, we ask for your help in ensuring that these tools are not misused or abused.

Sincerely,

Kathleen Sebelius
Secretary
U.S. Department of Health & Human Services

Eric H. Holder, Jr.
Attorney General
U.S. Department of Justice

EHR DOCUMENTATION

- Metadata
  - Data about data
  - Discoverable
- Clinical decision support tools
  - Large number
  - Inaccurate/irrelevant
  - Metadata

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Monday, January 27, 2020

Electronic Health Records Vendor to Pay $145 Million to Resolve Criminal and Civil Investigations

Practice Fusion Inc. Admits to Kickback Scheme Aimed at Increasing Opioid Prescriptions

Practice Fusion Inc. (Practice Fusion), a San Francisco-based health information technology developer, will pay $145 million to resolve criminal and civil investigations relating to its electronic health records (EHR) software, the Department of Justice announced today.

As part of the criminal resolution, Practice Fusion admits that it solicited and received kickbacks from a major opioid company in exchange for utilizing its EHR software to influence physician prescribing of opioid pain medications. Practice Fusion has executed a deferred prosecution agreement and agreed to pay over $26 million in criminal fines and forfeiture. In separate civil settlements, Practice Fusion has agreed to pay a total of approximately $118.6 million to the federal government and states to resolve allegations that it accepted kickbacks from the opioid company and other pharmaceutical companies and also caused its users to submit false claims for federal incentive payments by misrepresenting the capabilities of its EHR software.

"Across the country, physicians rely on electronic health records software to provide vital patient data and unbiased medical information during critical encounters with patients," said Principal Deputy Assistant Attorney General Ethan Davis of the Department of Justice's Civil Division. "Kickbacks from drug companies to software vendors that are designed to improperly influence the physician-patient relationship are unacceptable. When a software vendor claims to be providing unbiased medical information – especially information relating to the prescription of opioids – we expect honesty and candor to the physicians making treatment decisions based on that information."

www.justice.gov/opa/pr/electronic-health-records-vendor-pay-145-million-resolve-criminal-and-civil-investigations-0

EHR DOCUMENTATION

Thoroughly understand the operation of the EHR that you are using.

Assure that each patient encounter is accurately portrayed in the documentation.

MEDICAL MARIJUANA

State Approaches to Marijuana

(Non-exclusive)

Decriminalization

Medical

Recreational

TERMINOLOGY

- Cannabis: plant family that has many species, including
  - Hemp
    - Low THC levels
    - High CBD levels
    - Effect: relaxing, calming
  - Marijuana
    - High THC levels – gets users high
    - Low CBD levels
    - Effect: psychoactive

FEDERAL LAW

- Marijuana is a Schedule I controlled substance
  - Defined as drugs with no currently accepted medical use and a high potential for abuse
  - It is illegal to prescribe Schedule I drugs
  - It is illegal to help people illegally possess Schedule I drugs
  - Examples of Schedule I drugs are:
    - heroin
    - lysergic acid diethylamide (LSD)
    - marijuana (cannabis)
    - 3,4-methylenedioxymethamphetamine (ecstasy)
    - methaqualone
    - peyote

FEDERAL LAW

Exceptions

- Three FDA-approved medications from marijuana
  - Epidiolex – Schedule V
    - Patients 2 and over
    - Seizures associated with Lennox-Gestaut Syndrome or Dravet Syndrome
  - Marinol – Schedule III
    - Adults
    - Anorexia associated with AIDS
    - Nausea and vomiting associated with chemo
  - Cesamet – Schedule II
    - Adults
    - Nausea and vomiting associated with chemo

FEDERAL LAW

Consequences of marijuana being Schedule I/illegal

- Federal law prohibits firearm sales to marijuana users
  - Federal law prohibits any person who is an unlawful user of or addicted to any controlled substance from possessing firearms
    - Marijuana use is illegal
    - No exception for use allowed under state law

3. Place of Birth		4. Height	5. Weight	6. Sex	7. Birth Date		
U.S. City and State **-OR-**	Foreign Country	Ft. ___ In. ___	*(Lbs.)*	☐ Male ☐ Female	Month	Day	Year

8. Social Security Number *(**Optional**, but will help prevent misidentification)*	9. Unique Personal Identification Number *(UPIN)* if applicable *(See Instructions for Question 9.)*

10.a. Ethnicity	10.b. Race ***(In addition to ethnicity, select one or more race in 10.b. Both 10.a. and 10.b. must be answered.)***		
☐ Hispanic or Latino	☐ American Indian or Alaska Native	☐ Black or African American	☐ White
☐ Not Hispanic or Latino	☐ Asian	☐ Native Hawaiian or Other Pacific Islander	

11. Answer the following questions by checking or marking ***"yes"*** or ***"no"*** in the boxes to the right of the questions.	Yes	No
a. Are you the actual transferee/buyer of the firearm(s) listed on this form? **Warning: You are not the actual transferee/buyer if you are acquiring the firearm(s) on behalf of another person. If you are not the actual transferee/buyer, the licensee cannot transfer the firearm(s) to you.** *Exception: **If you are picking up a repaired firearm(s)** for another person, you are **not** required to answer 11.a. and may proceed to question 11.b. (See Instructions for Question 11.a.)*	☐	☐
b. Are you under indictment or information in any court for a **felony**, or any other crime for which the judge could imprison you for more than one year? *(See Instructions for Question 11.b.)*	☐	☐
c. Have you ever been convicted in any court of a **felony**, or any other crime for which the judge could have imprisoned you for more than one year, even if you received a shorter sentence including probation? *(See Instructions for Question 11.c.)*	☐	☐
d. Are you a fugitive from justice? *(See Instructions for Question 11.d.)*	☐	☐
e. Are you an unlawful user of, or addicted to, marijuana or any depressant, stimulant, narcotic drug, or any other controlled substance? **Warning: The use or possession of marijuana remains unlawful under Federal law regardless of whether it has been legalized or decriminalized for medicinal or recreational purposes in the state where you reside.**	☐	☐

FEDERAL LAW

Consequences of marijuana being Schedule I/illegal

- Federal law prohibits firearm sales to marijuana users
  - Cannot sell to buyer if
    - Buyer marked “yes” to question 11
    - Buyer uses marijuana card for ID or proof of residency
      - Even if “no” to question 11

U.S. Department of Justice

Bureau of Alcohol, Tobacco,
Firearms and Explosives

Washington DC 20226

September 21, 2011

www.atf.gov

OPEN LETTER TO ALL FEDERAL FIREARMS LICENSEES

The Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) has received a number of inquiries regarding the use of marijuana for medicinal purposes[1] and its applicability to Federal firearms laws. The purpose of this open letter is to provide guidance on the issue and to assist you, a Federal firearms licensee, in complying with Federal firearms laws and regulations.

A number of States have passed legislation allowing under State law the use or possession of marijuana for medicinal purposes, and some of these States issue a card authorizing the holder to use or possess marijuana under State law. During a firearms transaction, a potential transferee may advise you that he or she is a user of medical

FEDERAL LAW

Consequences of marijuana being Schedule I/illegal

- It is illegal to “prescribe” marijuana
  - States use different terms
    - Federal government could still see it as illegal
- Healthcare systems may prohibit their physicians from talking to patients about cannabis treatment options
- Localities may ban in states that allow

FEDERAL ENFORCEMENT IN STATES ALLOWING MARIJUANA

DOJ enforcement memos

- 2009 – "Ogden Memo" – medical marijuana
- 2013 – "Cole Memo" – medical and recreational marijuana
- Guidance only – not binding
- Both listed conditions which, if met by state, would deprioritize federal prosecution
  - Prosecution would still be considered if
    - Sales to minors, unlawful use of firearms, etc.

Office of the Attorney General
Washington, D. C. 20530

January 4, 2018

MEMORANDUM FOR ALL UNITED STATES ATTORNEYS

FROM: Jefferson B. Sessions, III
Attorney General

SUBJECT: Marijuana Enforcement

In the Controlled Substances Act, Congress has generally prohibited the cultivation, distribution, and possession of marijuana. 21 U.S.C. § 801 *et seq*. It has established significant penalties for these crimes. 21 U.S.C. § 841 *et seq*. These activities also may serve as the basis for the prosecution of other crimes, such as those prohibited by the money laundering statutes, the unlicensed money transmitter statute, and the Bank Secrecy Act. 18 U.S.C. §§ 1956-57, 1960; 31 U.S.C. § 5318. These statutes reflect Congress's determination that marijuana is a dangerous drug and that marijuana activity is a serious crime.

In deciding which marijuana activities to prosecute under these laws with the Department's finite resources, prosecutors should follow the well-established principles that govern all federal prosecutions. Attorney General Benjamin Civiletti originally set forth these principles in 1980, and they have been refined over time, as reflected in chapter 9-27.000 of the

https://www.justice.gov/opa/press-release/file/1022196/download

FEDERAL ENFORCEMENT IN STATES ALLOWING MARIJUANA

2014 Congressional Budget Amendment

- Prohibiting DOJ from using funds to prevent states from implementing their medical marijuana laws
- Rohrabacher Amendment

FEDERAL ENFORCEMENT - THE KETTLE FALLS FIVE CASE

- 2013: indictment
- 2014: Congressional amendment prohibiting DOJ from using funds to prevent states from implementing their medical marijuana laws
- 2015: prosecution continues
- 2017: feds finally agreed – no $ to prosecute
  - But doesn't drop charges
- January 2018: case dropped, but "without prejudice"
  - Can be brought again
- June 2018: Statute of limitations ran out

US v. McIntosh, 833 F.3d 1163 (9th Cir. 2018)

PENNSYLVANIA MEDICAL MARIJUANA

SENATE BILL 3

- On April 17, 2016, Governor Tom Wolf signed into law SB 3, legalizing medical marijuana in Pennsylvania
- “I am proud to sign this bill that will provide long overdue medical relief to patients and families who could benefit from this treatment.” – Gov. Wolf

DEFINITIONS

- “Medical marijuana” refers to marijuana for certified medical use under the Act.
- “Practitioner” means a physician who is registered with the department under section 401.
- “Prescription drug monitoring program” means the Achieving Better Care by Monitoring All Prescriptions Program (ABC-MAP)

35 P.S. § 10231.103

QUALIFIED MEDICAL CONDITIONS

- Amyotrophic lateral sclerosis.
- Autism.
- Cancer, including remission therapy.
- Crohn's disease.
- Damage to the nervous tissue of the central nervous system (brain-spinal cord) with objective neurological indication of intractable spasticity, and other associated neuropathies.
- Dyskinetic and spastic movement disorders.
- Epilepsy.
- Glaucoma.
- HIV / AIDS.
- Huntington's disease.
- Inflammatory bowel disease.
- Intractable seizures.
- Multiple sclerosis.
- Neurodegenerative diseases.
- Neuropathies.
- Opioid use disorder for which conventional therapeutic interventions are contraindicated or ineffective, or for which adjunctive therapy is indicated in combination with primary therapeutic interventions.
- Parkinson's disease.
- Post-traumatic stress disorder.
- Severe chronic or intractable pain of neuropathic origin or severe chronic or intractable pain.
- Sickle cell anemia.
- Terminal illness.

35 P.S. § 10231.103

LAWFUL USE OF MEDICAL MARIJUANA

Medical marijuana may only be dispensed in the following forms:

i. Pill;
ii. Oil;
iii. Topical forms, including gels, creams or ointments;
iv. A form a form medically appropriate for administration by vaporization or nebulization, excluding dry leaf or plant form until dry leaf or plant forms become acceptable under regulations adopted under section 1202;
v. Tincture; or
vi. Liquid.

35 P.S. § 10231.303

UNLAWFUL FORMS

- Medical marijuana may NOT be dispensed to a patient in dry leaf or plant form
- Smoking medical marijuana is prohibited
- Edible medical marijuana is prohibited

35 P.S. § 10231.303; § 10231.304

PRACTITIONER REGISTRATION

To be eligible to issue certifications to patients to use medical marijuana, a physician must:

1. Apply for registration in the registry in the form and manner required by the department;
2. Department must determine the physician is qualified to treat serious medical condition;
3. The physician must have successfully completed the course under section 301(a)(6).

35 P.S. § 10231.401

MEDICAL MARIJUANA TRAINING COURSE

- A four-hour training course physicians, pharmacists, certified registered nurse practitioners and physician assistants regarding the latest scientific research on medical marijuana, including the risks and benefits of medical marijuana, and other information deemed necessary by the department.
- Approved as continuing education credits

35 P.S. § 10231.301.

ISSUANCE OF CERTIFICATION FOR MEDICAL MARIJUANA

A certification to use medical may be issued if ALL of the following are met:

1. The practitioner has been approved by the department for inclusion in the registry and has a valid, unexpired, unrevoked, unsuspended Pennsylvania license to practice medicine at the time of the issuance of the certification;
2. The practitioner has determined the patient has a serious medical condition;
3. The patient is under the practitioner's continuing care for the serious medical condition;
4. The practitioner determiners that the patient is likely to receive therapeutic or palliative benefit from the use of medical marijuana; AND
5. The practitioner has consulted the PMP prior to issuing a certification and prior to recommending a change of amount or form of medical marijuana

35 P.S. § 10231.403

ISSUANCE OF CERTIFICATION FOR MEDICAL MARIJUANA

- Duties of practitioner – The practitioner shall:
  1. Provide the certification to the patient
  2. Provide a copy of the certification to the department
  3. File a copy of the certification in the patient's health care record

- Prohibition – A practitioner may not issue a certification for the practitioner's own use or for the use of a family or household member.

35 P.S. § 10231.403

DURATION OF MEDICAL MARIJUANA SUPPLY

- Receipt of medical marijuana by a patient or caregiver from a dispensary may not exceed a 30-day supply of individual doses

35 P.S. § 10231.405

PRACTITIONER REQUIREMENTS AFTER PRESCRIBING

A practitioner has an ongoing responsibility to immediately notify the department in writing if the practitioner knows or has reason to know that any of the following is true with respect to a patient:

1. The patient no longer has a serious medical condition;
2. Medical marijuana would no longer be therapeutic or palliative;
3. The patient has died.

35 P.S. § 10231.401

PRACTITIONER RESTRICTIONS

- A practitioner may not accept, solicit or offer any form of remuneration from a prospective patient to determine if prospective patient should be certified to use medical marijuana.
- A practitioner may not hold a direct or economic interest in a medical marijuana organization.
- A practitioner may not advertise the practitioner's services as a practitioner who can certify a patient to receive medical marijuana.
- Violation = unprofessional conduct
  - Off registry
  - Discipline by licensing board

35 P.S. § 10231.402

MARIJUANA POLICY PROJECT

A GUIDE FOR DOCTORS AND PATIENTS

What *must* a doctor do before making a certification?

- Be currently licensed and in good standing
- Be responsible for the ongoing care of the patient
- Include in the medical records of the patient a diagnosis of a qualifying condition
- Complete a four-hour course developed by the Department of Health
- Register with the health department

What *can't* a doctor do when making a certification?

- Conduct an exam using telemedicine technology
- Receive pay from or refer patients to marijuana businesses
- Conduct an exam at a location where medical marijuana is sold
- Have a direct or indirect economic interest in a cultivator or dispensary
- Advertise in a cultivation center or dispensary
- Help patients obtain marijuana or offer advice on usage

www.mpp.org/states/pennsylvania/pennsylvanias-medical-marijuana-law-guide-doctors-patients/

GOAL –
GET FAMILIAR WITH MEDICAL MARIJUANA

Specifically:

- Understand medical marijuana
- Know the side effects
- Know how it can worsen other medical conditions

GOAL –
GET FAMILIAR WITH MEDICAL MARIJUANA

Recommended reading list - for all:

- *Contemporary Routes of Cannabis Consumption: A Primer for Clinicians*
  - Peters and Chien, Journal of the American Osteopathic Association, Feb. 2018
- *Medical Marijuana: Do the Benefits Outweigh the Risks?*
  - Gupta and Phalen, Current Psychiatry, Jan. 2018
- *Marijuana and the Psychiatric Patient*
  - Woodward, Psychiatric Times, Apr. 10, 2017

KEEP AT LEAST THESE POINTS IN MIND

- Little scientific literature to support benefits
  - Potential drug interactions are unknown
  - BIG problem for psychiatrists
- Drug is unregulated
  - Purity?
  - Potency?
- With minors:
  - Effects on brain development
  - Very risky
- Potential for abuse
- Potential for psychiatric and other side effects

LEVEL OF CONFIDENCE IN THE EVIDENCE FOR ADVERSE EFFECTS RELATED TO MARIJUANA

- HIGH
  - Addiction to marijuana
  - Diminished life achievement
  - Motor vehicle accidents
  - Chronic bronchitis
- MEDIUM
  - Abnormal brain development
  - Progression to other drugs
  - Schizophrenia
  - Depression and anxiety

Volkow ND et al. Adverse Health Effects of Marijuana Use. N Engl J Med 2014 June 5; 370(23): 2219-2227, www.ncbi.nlm.nih.gov/pmc/articles/PMC4827335/

LIABILITY OVERVIEW: MEDICAL MALPRACTICE LAWSUITS

Currently, no ***reported*** cases

- Cases could exist
- 4 elements of medical malpractice:
  - Duty of care
    - Likely to be recognized
  - Breach of duty (negligence)
    - Ex: failing to take adequate history
  - Harm
    - Ex: drug interaction
  - Causation (harm was caused by negligence)

LIABILITY OVERVIEW: MEDICAL MALPRACTICE LAWSUITS

"Authorizing physicians to certify or recommended medical marijuana does not, in any way, absolve them from rendering competent and scientifically informed medical care. Physicians…must understand that…they are recommending or certifying a non-FDA approved treatment that is not supported or recognized by the large majority of their professional colleagues. Doing so may expose them to malpractice liability no differently than if they prescribed any other potentially hazardous and scientifically controversial experimental treatment."

Marlowe DB, Malpractice Liability and Medical Marijuana, The Health Lawyer, Vol. 29, No. 2, December 2016

LIABILITY OVERVIEW: MEDICAL MALPRACTICE LAWSUITS

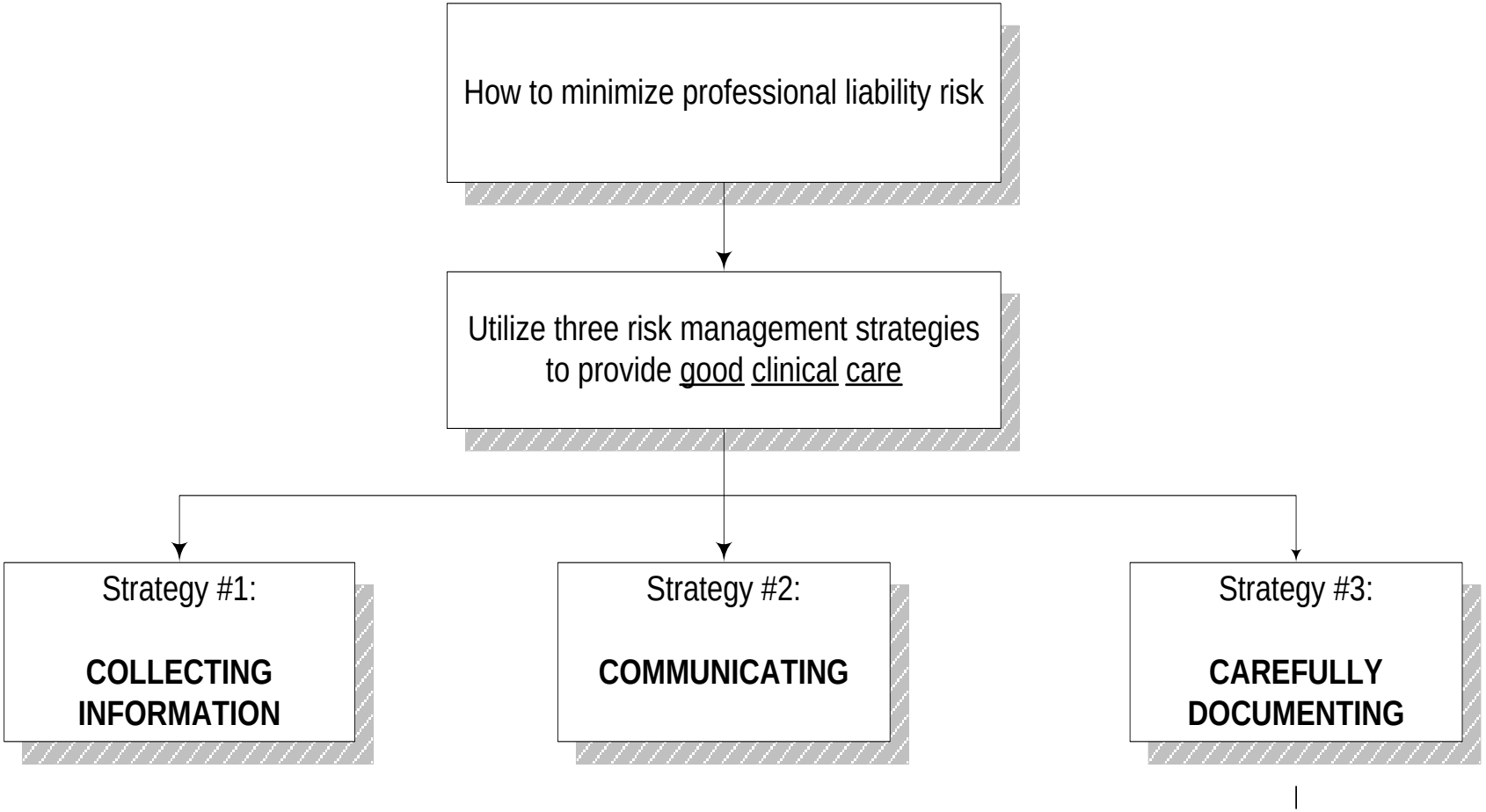
Professional liability insurance

- Policies exclude coverage for
  - Criminal acts
  - Statutory violations
  - Illegal acts

LIABILITY OVERVIEW: LICENSING BOARD ACTIONS

MANY reported cases

- Involved physicians who
  - Work in offices whose sole purpose is to sign medical marijuana certificates
  - Recommended for pregnant women
  - Recommended without medical necessity
  - Recommended without a legitimate doctor-patient relationship
  - Acted incompetently – recommended medical marijuana
    - Without appropriate examinations
    - Without creating appropriate medical records
    - After seeing patients at marijuana dispensaries instead of an office



RISK MANAGEMENT STRATEGIES TO ↑ INCREASE PATIENT SAFETY AND ↓ PROFESSIONAL LIABILITY

Strategy #1: COLLECT INFORMATION

- About the patient
  - History
  - Examination
  - Check the PMP
- About the medication
  - Including APA statement
- About treatment standards
  - NY
  - FSMB
  - CA

FSMB: MODEL GUIDELINES FOR THE RECOMMENDATION OF MARIJUANA IN PATIENT CARE

Guidelines

- Physician-Patient Relationship
- Patient Evaluation
- Informed and Shared Decision Making
- Treatment Agreement
- Qualifying Conditions
- Ongoing Monitoring and Adapting the Treatment Plan
- Consultation and Referral
- Medical Records
- Physician Conflict of Interest

www.fsmb.org/globalassets/advocacy/policies/model-guidelines-for-the-recommendation-of-marijuana-in-patient-care.pdf

MEDICAL BOARD OF CALIFORNIA: GUIDELINES FOR THE RECOMMENDATION OF CANNABIS FOR MEDICAL PURPOSES

Guidelines

- Physician-Patient Relationship
- Patient Evaluation
- Informed and Shared Decision Making
- Treatment Agreement
- Qualifying Conditions
- Ongoing Monitoring and Adapting the Treatment Plan
- Consultation and Referral
- Medical Records
- Physician Conflict of Interest

www.mbc.ca.gov/Publications/guidelines_cannabis_recommendation.pdf

RISK MANAGEMENT STRATEGIES TO ↑ INCREASE PATIENT SAFETY AND ↓ PROFESSIONAL LIABILITY

Strategy #2: COMMUNICATE

- With patient
  - Risks and benefits
    - Including risk of addiction
    - Side effects
  - Do not drive while intoxicated
- With others
  - Other prescribers

RISK MANAGEMENT STRATEGIES TO ↑ INCREASE PATIENT SAFETY AND ↓ PROFESSIONAL LIABILITY

Strategy #3: CAREFULLY DOCUMENT

- Medical record
- Informed consent
- Treatment plan/agreement
- Assessments
- Checking PMP

Medical Marijuana Certifications

Established physician-patient relationship?

No | Yes

DRUG "PUSHER"

Outside of established treatment relationship

Failure to follow established standards
- No history
- No physical exam
- No informed consent discussion

Clinically inappropriate
- No diagnosis
- No evidenced-based support
- Pregnant women

LEGITIMATE PATIENT CARE

Within established treatment relationship

Established standards are followed:
- History
- Physical exam
- Informed consent discussions
  - ✓ Documented
- Sufficient clinical basis
  - ✓ Diagnosis and evidenced-based support
  - ✓ Documented
- Patient monitoring
- Medical record

CONCLUSION AND CLINICAL PEARLS

- Federal law
  - Marijuana is Schedule I, so illegal to prescribe
  - Federal enforcement is unclear
  - Health systems may prohibit medical marijuana discussions with patients

- Pennsylvania law
  - Ensure compliance with all requirements
  - Watch for changes to requirements

CONCLUSION AND CLINICAL PEARLS

- Clinically
  - Get up to speed with marijuana
    - Even if you don't certify, your patients may be on it
  - If you want to certify:
    - May be difficult in psychiatry
      - Need evidence-based support
    - Must be within physician-patient treatment relationship
    - In the absence of state guidelines, follow those from FSMB
    - Utilize the 3 Cs – practice good medicine
      - Collect information
      - Communicate
        - Consider a treatment plan
      - Carefully document
- Professional liability exposure
  - Licensing board action more likely than med mal lawsuit
  - Med mal insurance policies exclude coverage for illegal acts

QUESTIONS?