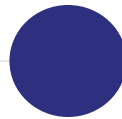


# PSYCHIATRIC RISK MANAGEMENT UPDATES



**Donna Vanderpool, MBA, JD**  
Director of Risk Management

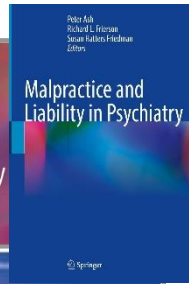
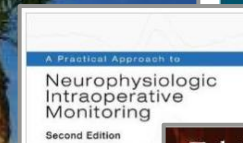
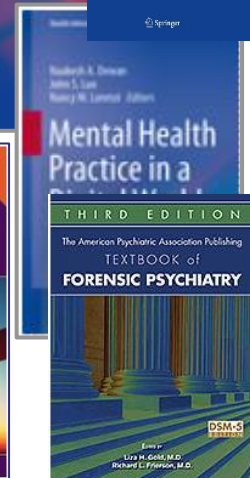
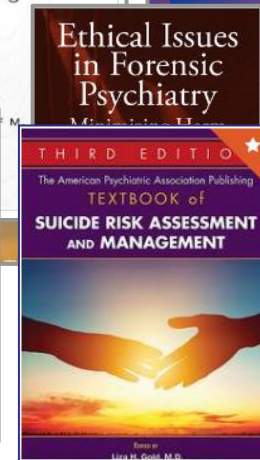
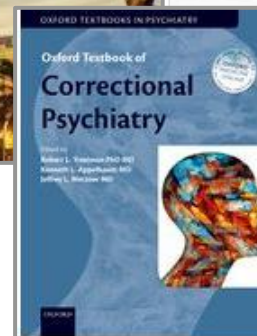
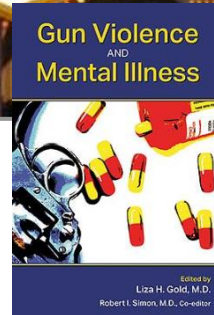
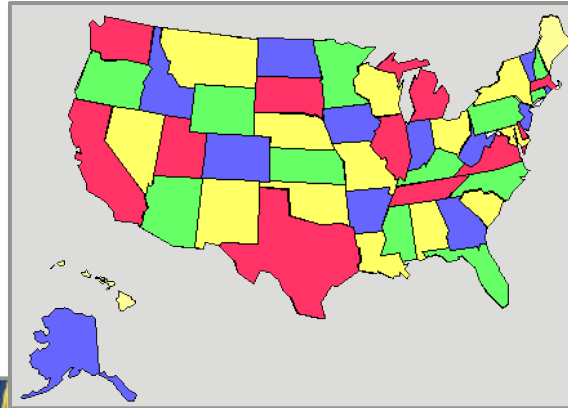
**Justin Pope, JD**  
Senior Risk Manager

Professional Risk Management Services (PRMS)

**March 1, 2024**  
**Baton Rouge, LA**

The speakers have no financial relationships with ineligible companies to disclose

# DONNA VANDERPOOL, MBA, JD



# AGENDA

- Introduction
- Technology
  - Telepsychiatry
  - EHRs
  - Social media
- Psychopharmacology
- 10 things about....





## Psychiatric Risk Management Updates - March 1, 2024

To apply for CME credit, click [here](#).

To access Handout slides, click [here](#).

### Additional Resources

#### PRMS Resources

- [Telepsychiatry\\_Regulatory\\_Fact\\_Sheet](#)
- [Treating\\_Out-of-State\\_College\\_Students](#)
- [10\\_Things\\_about\\_Telepsychiatry](#)
- [EHR\\_Vendor\\_Contracts](#)
- [10\\_Things\\_about\\_Social\\_Media](#)
- Psychopharmacology newsletters
  - [Part\\_1](#)
  - [Part\\_2](#)
- [Practical\\_Pointers\\_for\\_Using\\_a\\_Collection\\_Agency](#)
- [To\\_Collect\\_or\\_Not\\_to\\_Collect?](#)
- [Documentation\\_newsletter](#)
- [Informed\\_Consent](#)
- Suicide newsletters
  - [Part\\_1](#)
  - [Part\\_2](#)
- [Reducing\\_Risk\\_When\\_Treating\\_Potentially\\_Violent\\_Patients](#)
- [Patient\\_Violence\\_Against\\_Clinicians](#)
- [Supervision\\_of\\_Nurse\\_Practitioners](#)
- [Practical\\_Pointers\\_for\\_Treating\\_Geropsychiatric\\_Patients](#)
- [Termination\\_of\\_the\\_Physician-Patient\\_Relationship](#)
- [Office\\_Sharing\\_and\\_Liability\\_Risks](#)
- [Failing\\_to\\_Plan...is\\_Planning\\_to\\_Fail](#)

#### Articles Authored by PRMS Risk Managers in *Innovations in Clinical Neuroscience*

- [EHR\\_Documentation:\\_How\\_to\\_Keep\\_Your\\_Patients\\_Safe,\\_Keep\\_Your\\_Hard-Earned\\_Money,\\_and\\_Stay\\_Out\\_of\\_Court](#)
- [What\\_Can\\_I\\_Do\\_about\\_a\\_Negative\\_Online\\_Review?](#)
- [Consent\\_to\\_Treatment\\_of\\_Minors](#)
- [Managing\\_Your\\_Aging\\_Patient\\_Population](#)
- [Myths\\_&\\_Misconceptions:\\_Terminating\\_Treatment](#)
- [Emergency\\_Planning](#)

#### Additional Resource

- [Suicide\\_Assessment\\_and\\_Treatment\\_Course\\_2023](#) – free on-demand course from McLean/Stanford (no CME)

Professional Risk Management Services (PRMS)  
Cause of Loss – Administrative Actions, Claims, and Lawsuits

1986 - 2023

<b>Primary Allegation</b>	<b>All States</b>	<b>LA</b>	<b>MS</b>
Suicide / Attempted Suicide	28%	18%	18%
Incorrect Treatment	21%	31%	38%
Breach of Confidentiality	14%	4%	10%
Other	12%	1%	6%
Medication Issues	8%	15%	10%
Incorrect Diagnosis	5%	7%	7%
Unnecessary Commitment	3%	14%	5%
Improper Supervision	3%	7%	2%
Boundary Violation	3%	1%	3%
Abandonment	1%	1%	--
Duty to Warn / Protect	1%	1%	< 1%
Forensic	< 1%	--	--
Lack of Informed Consent	< 1%	--	< 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

PROFESSIONAL RISK MANAGEMENT SERVICES (PRMS)  
 CAUSE OF LOSS – CLAIMS AND LAWSUITS  
 2014 – 2023

Primary Allegation	Adult Patients	Minor Patients
Incorrect Treatment	31%	24%
Medication Issues	17%	17%
Suicide / Attempted Suicide	14%	22%
Hospital Commitment / Discharge	7%	5%
Other	11%	12%
Misdiagnosis	8%	0
Breach of Confidentiality	5%	5%
Improper Supervision	4%	15%
Boundary Violation	2%	0
Duty to Warn / Protect	<1%	0
Abandonment	<1%	0

Notes:

- Data set has only those claims and suits with patient ages documented – not all claims and suits
- “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

## 1) Duty of Care

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

## 2) Breach of Duty

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

## 3) Damages

The patient suffered an adverse outcome (injury)

## 4) Causation

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

# 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
- Accreditation standards
- Facility's own policies and procedures
- Drug label / manufacturer recommendations
- Etc.

# ADMINISTRATIVE ACTIONS

- Take them seriously!
- No damages required
- Increased attention to professional discipline
- Call your insurer

# AGENDA

- Introduction
- Technology
  - Telepsychiatry
  - EHRs
  - Social media
- Psychopharmacology
- 10 things about....



# WHAT WE KNOW

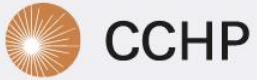
WE KNOW STATE LAW MUST BE MET

# STATE LICENSURE REQUIREMENTS MATTER!

- You are in a regulated profession
  - You can only practice where you meet licensure requirements
  - Risk = unauthorized practice of medicine
- Consequences of being found to be engaged in the unauthorized practice of medicine
  - That state may discipline you
  - States where you are licensed may discipline you
  - You have no liability insurance coverage for illegal acts
- You need to meet licensure requirements even if you are not prescribing

# STATE ISSUE - LICENSURE

- State law where you are PLUS state law where patient is
  - Patient's state of residency is irrelevant
- States vary
  - Special telemedicine license
  - Exception to licensure in statute
  - Limited number of sessions per year
  - Licensing board may allow sessions for continuity of care without license



Look up policy by:

Topic ▼

Federal

State ▼

# CCHP is the National Telehealth Policy Resource Center

The Center for Connected Health Policy is a nonprofit, nonpartisan organization working to maximize telehealth's ability to improve health outcomes, care delivery, and cost effectiveness. Our expertise in telehealth policy was recognized in 2012, when we became the federally designated National Telehealth Policy Resource Center.

[LEARN MORE ABOUT OUR WORK](#)



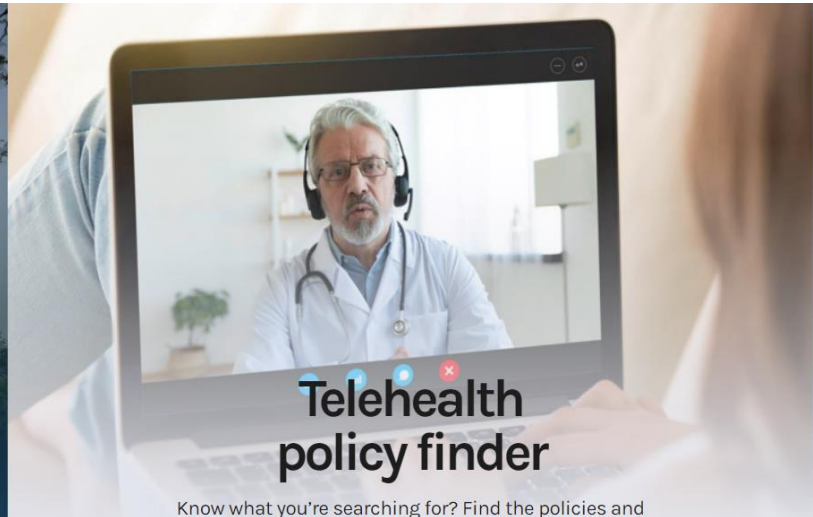
<https://www.cchpca.org/>



# Understanding telehealth policy




Get to know how the laws, regulations, and Medicaid programs work in your state.

-  How we work
-  Resources & reports
-  Ask a policy expert



# Telehealth policy finder

Know what you're searching for? Find the policies and regulations that impact you.

-  All telehealth policies
-  COVID-19 actions
-  Pending legislation



<https://www.cchpca.org/>



We track telehealth-related laws and regulations across three categories and 19 unique topics. Click on a topic to see how it's applied in your state.

## Professional Requirements

[DEFINITIONS >](#)

[CONSENT REQUIREMENTS >](#)

[ONLINE PRESCRIBING >](#)

[CROSS-STATE LICENSING >](#)

[LICENSURE COMPACTS >](#)

[PROFESSIONAL BOARDS STANDARDS >](#)

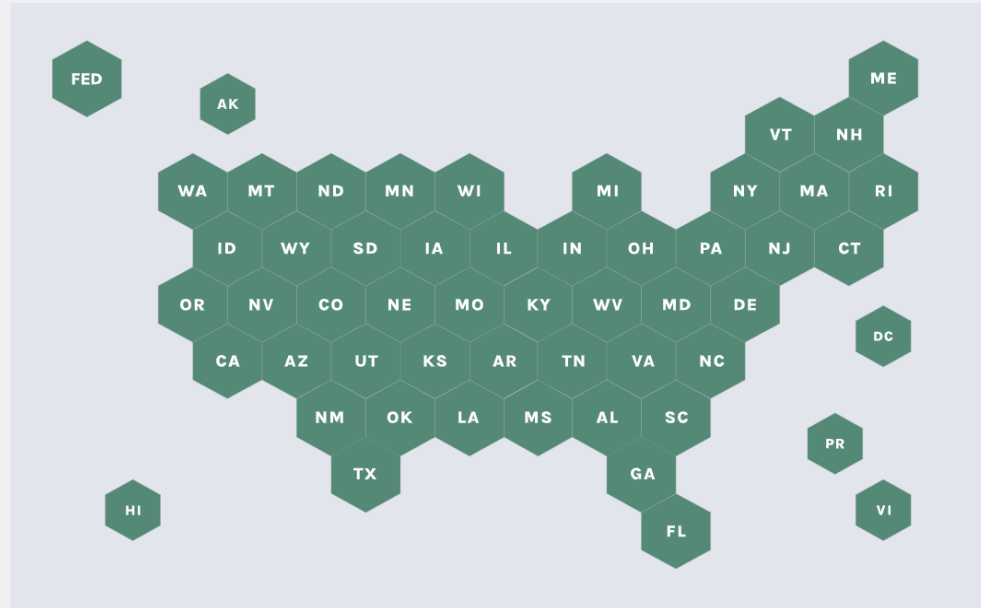
[MISCELLANEOUS >](#)

<https://www.cchpca.org/all-telehealth-policies/>

## PROFESSIONAL REQUIREMENTS

# Cross-State Licensing

When telehealth is used, it is considered to be rendered at the physical location of the patient, and therefore a provider typically needs to be licensed in the patient's state. A few states have licenses or telehealth specific exceptions that allow an out-of-state provider to render services via telemedicine in a state where they are not located, or allow a clinician to provide services via telehealth in a state if certain conditions are met (such as agreeing that they will not open an office in that state). Still other states have laws that don't specifically address telehealth and/or telemedicine licensing, but make allowances for practicing in contiguous states, or in certain situations where a temporary license might be issued provided the specific state's licensing conditions are met.



CLICK THE MAP TO SCROLL DOWN TO THE STATE

<https://www.cchpca.org/topic/cross-state-licensing-professional-requirements/>

# Florida

*Last updated 01/26/2023*

A health care professional not licensed in this state may provide health care services to a patient located in this state using telehealth if the health care professional registers with the applicable board, or the department if there is no board, and provides health care services within the applicable scope of practice established by Florida law or rule.

See law for specific provider requirements.

An out-of-state provider must have professional liability coverage or financial responsibility that includes coverage for telehealth services provided to patients not located in the provider's home state. A health care professional registered under this section may not open an office or provide in-person services. The Department is required to publish all registrants on its website with specific requirements outlined in the law.

SOURCE: [FL Statute 456.47](#) & [Florida Board of Medicine](#). (Accessed Jan. 2023).

**READ LESS**



As of the effective date of this rule, the Board will no longer issue what was previously termed a “telemedicine license.” Individuals previously granted a telemedicine license under the former version of this rule may apply to have the license converted to a full license. Such individuals must complete the application for a full license and provide all necessary documentation, though no new application fee will be required as long as application is made within two years of the effective date of this rule. See rule for details for individuals who do not convert to a full license.

SOURCE: [TN Rule Annotated, Rule 0880-02.-16. \(Accessed Mar. 2023\).](#)

The TN Osteopathic Board will still issue a telemedicine license. See rule for details.

SOURCE: [TN Rule Annotated, Rule 1050.02.17.\(2\) \(Accessed Mar. 2023\).](#)

## Arizona

### Professional Requirements

#### DEFINITIONS

#### CONSENT REQUIREMENTS

#### ONLINE PRESCRIBING

#### CROSS-STATE LICENSING

#### LICENSURE COMPACTS

#### PROFESSIONAL BOARDS STANDARDS

#### MISCELLANEOUS

# Cross State Licensing

A health care provider who is not licensed in Arizona may provide telehealth services to a person located in Arizona if the health care provider complies with all of the following:

1. Registers with the state's applicable health care provider regulatory board or agency that licenses comparable health care providers on an application prescribed by the board or agency that contains certain elements (see law text).
2. Before prescribing a controlled substance to a patient, registers with the controlled substances prescription monitoring program.
3. Pays the registration fee as determined by the applicable health care provider regulatory board or agency.
4. Holds a current, valid and unrestricted license to practice in another state that is substantially similar to a license issued in Arizona to a comparable health care provider and is not subject to any past or pending disciplinary proceedings in any jurisdiction. The health care provider shall notify the applicable health care provider regulatory board or agency within five days after any restriction is placed on the health care provider's license or any disciplinary action is initiated or imposed. The health care provider regulatory board or agency registering the health care provider may use the national practitioner databank to verify the information submitted.

**DEFINITIONS**

**CONSENT REQUIREMENTS**

**ONLINE PRESCRIBING**

**CROSS-STATE LICENSING**

**LICENSURE COMPACTS**

**PROFESSIONAL BOARDS  
STANDARDS**

**MISCELLANEOUS**

A health care provider who is not licensed to provide health care services in Arizona but who holds an active license to provide health care services in another jurisdiction and who provides telehealth services to a person located in Arizona is not subject to the registration requirements of this section if either of the following applies:

- The services are provided under one of the following circumstances:
  - In response to an emergency medication condition.
  - In consultation with a health care provider who is licensed in Arizona and who has the ultimate authority over the patient's diagnosis and treatment.
  - To provide after-care specifically related to a medical procedure that was delivered in person in another state.
  - To a person who is a resident of another state and the telehealth provider is the primary care provider or behavioral health provider located in the person's state of residence.
- • The health care provider provides fewer than ten telehealth encounters in a calendar year.

SOURCE: [AZ Revised Statute Sec. 36-3606 \(Accessed Jan. 2023\)](#).

# **NORTH CAROLINA § 90-18**

## **PRACTICING WITHOUT LICENSE**

(c) The following shall not constitute practicing medicine or surgery as defined in this Article:

...

(18) The practice of medicine by any nonregistered physician residing in another state or foreign country who is contacted by one of the physician's regular patients for treatment by use of any method of communication while the physician's patient is temporarily in this State.

# MEETING LICENSURE REQUIREMENTS IN PATIENT'S STATE

- **Option #1** – determine if you can continue treating patient in state where you are not licensed
  - Initial research – exception to licensure?
  - Contact licensing board to confirm license is actually needed, stressing:
    - NOT currently doing it
    - Existing patient
    - Board certification(s)
    - If only for a limited time
    - If not prescribing CS, or any meds

# MEETING LICENSURE REQUIREMENTS IN PATIENT'S STATE

- Option #2 – get licensed in that state
  - BUT...likely will not be able to prescribe controlled  
Need federal DEA registration in that state, but that requires a brick-and-mortar office in patient's state
- Option #3 – wing it and hope no consequences
  - Understand the known risk
  - Additional risk is possible

# MEETING STATE LICENSURE REQUIREMENTS

- If you cannot meet licensure requirements:
  - You do not want to be found engaged in the unauthorized practice of medicine
    - Insurance issues
    - Discipline from all relevant boards
  - You need to terminate the treatment relationship
    - Unless patient can come into your state to be treated



Search Psychiatry.org

- Psychiatrists Residents & Medical Students Patients and Families Membership

## Find a Psychiatrist

A psychiatrist specializes in the diagnosis, treatment, and prevention of mental illness and substance abuse disorders. Psychiatrists are uniquely qualified to understand the complex interrelation between mental and physical health since their training includes four years of medical school and at least three additional years in a psychiatric residency. By using the Psychiatrist Locator you agree to the terms in the Usage Agreement.



Psychiatrists must explicitly opt-in to this database. Therefore, this is not representative of the number of psychiatrists throughout the nation or in any geographic area.

### QUICK SEARCH

Zip Code

Within

OR

Country

State

City

**SEARCH**

ADVANCED SEARCH

+ EXPAND

<http://finder.psychiatry.org/>



# CONSULTS - STATE LICENSURE REQUIREMENTS

- Consultations by out-of-state physicians
  - With other physicians – NOT with patients
  - Still need to ensure you are meeting licensure requirements
  - Many states have exception for consults
    - But may have conditions
      - All seem to require “occasional basis” or “periodic” or “episodic” or “does not provide consultation in this state on a regular or frequent basis”
      - Some specify other physician retains responsibility for treatment



# STATE ISSUE – PRESCRIBING CONTROLLED SUBSTANCES

- States have various restrictions
  - Not allowing CS to be prescribed via telemedicine
  - Limits on when CS can be prescribed via telemedicine
    - › ex: FL allows for psychiatric diagnosis
    - › ex: NH only allows for SUD treatment (except methadone)
  - Requiring in-person visit prior to prescribing CS via telemedicine
  - Requiring subsequent in-person visits when prescribing CS via telemedicine



We track telehealth-related laws and regulations across three categories and 19 unique topics. Click on a topic to see how it's applied in your state.

## Professional Requirements

[DEFINITIONS >](#)

[CONSENT REQUIREMENTS >](#)

[ONLINE PRESCRIBING >](#)

[CROSS-STATE LICENSING >](#)

[LICENSURE COMPACTS >](#)

[PROFESSIONAL BOARDS STANDARDS >](#)

[MISCELLANEOUS >](#)

<https://www.cchpca.org/all-telehealth-policies/>

A prescription for a controlled substance may only be issued as a result of telehealth medical services if each of the following apply:

- The telehealth visit includes synchronous audio or audio-visual communication using HIPAA compliant equipment with the prescriber responsible for the prescription.
- The prescriber has had at least one in-person encounter with the patient within the preceding 12 months.
- The prescriber has established a legitimate medical purpose for issuing the prescription within the preceding 12 months.

This subsection shall not apply in an in-patient setting.

## Medical State Licensure and/or Controlled Substance Licensure

### One License Requirement

Alaska  
Arizona  
Arkansas  
California  
Colorado  
Florida  
Georgia  
Kansas  
Kentucky  
Maine  
Minnesota  
Mississippi  
Montana  
Nebraska  
New Hampshire  
New York  
North Carolina  
North Dakota  
Ohio  
Oregon  
Pennsylvania  
Tennessee  
Texas  
Vermont  
Virginia  
Washington  
West Virginia  
Wisconsin

### Second CS License Requirement

Alabama  
Connecticut  
Delaware  
DC  
Guam  
Hawaii  
Idaho  
Illinois  
Indiana  
Iowa  
Louisiana  
Maryland  
Massachusetts  
Michigan  
Missouri  
Nevada  
New Jersey  
New Mexico  
Oklahoma  
Puerto Rico  
Rhode Island  
South Carolina  
South Dakota  
Utah  
Wyoming

# TELEMEDICINE STANDARD OF CARE

- Is the same standard of care that would apply if the patient was physically in the physician's office or facility
- Most states have explicitly addressed
  - By statute
  - By licensing board position statement

# STANDARD OF CARE TOPICS TYPICALLY ADDRESSED IN STATE TELEMEDICINE LAWS

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



# Informed consent for telehealth treatment

---

Preferred name:	<input type="text"/>	<input type="text"/>
	first	last
Name in medical record (if different):	<input type="text"/>	<input type="text"/>
	first	last
Date of birth (MM/DD/YYYY):	<input type="text"/>	
	date of birth (month/day/year)	

Please note that ongoing telehealth treatment with a Massachusetts-licensed mental health provider may not be available at this time if you are physically located outside of the state of Massachusetts. At the start of your visit, your provider will ask you for the address where you are receiving telehealth services in order to confirm that you are located in Massachusetts or in another location where such services are currently available and to ensure there is an accurate location for you in case of an emergency.

If a telehealth visit does not work for you for any reason, please let us know and alternative support options can be considered.

As always, 24/7 phone support is available to you by calling MIT Medical's Student Mental Health and Counseling Services (SMH&C) at 617-253-2916.

Prior to your telehealth visit, please read the below consent for telehealth treatment.

1. You retain the option to withhold or withdraw consent at any time without affecting your right to future care or treatment or risking the loss or withdrawal of any program benefits to which you would otherwise be entitled.
2. The laws that protect the confidentiality of your medical information also apply to telehealth. The information disclosed by you during the course of your treatment is generally confidential. Exceptions to confidentiality laws include the requirements to: protect you or the public from serious harm; report abuse or neglect of children, the elderly, or people with disabilities; and respond to an order from a court or other valid legal process such as a subpoena.
3. MIT contracts with Cerner as its remote service platform vendor, which is the HIPAA compliant tool by which telehealth services are provided. Cerner encrypts all audio, video, and screen sharing data as a means of protecting your personally identifiable information. Despite these efforts there are risks associated with telehealth. These may include, but are not limited to, the possibility that transmission of your medical information could be disrupted or distorted by technical failures; the transmission of your medical information could be interrupted by unauthorized persons; and/or misunderstandings between you and your provider can more easily occur. In addition, telehealth-based services and care may not yield the same results or be as effective as face-to-face service. If you or your provider believes you would be better served by face-to-face service, you may be referred to a provider in your area to receive such service. Finally, there are potential risks associated with any form of mental health treatment, and despite your efforts and the efforts of your provider, your condition may not improve, and in some cases may even get worse.
4. The benefits of telehealth may include removing transportation and travel barriers, minimizing time constraints, and providing greater opportunity to prepare in advance for treatment sessions.

# WHAT WE KNOW

## WE KNOW STATE LAW IS CHANGING

Resources:

- Center for Connected Healthcare Policy ([cchpca.org](http://cchpca.org))
- State medical association

# WHAT WE KNOW

WE KNOW THE DEA HAS TEMPORARILY  
CONTINUED THE PHE TELEMEDICINE  
FLEXIBILITIES

# FEDERAL LAW

- Controlled Substances Act (as amended by RHA)
  - “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”

# DEA *PROPOSED* REGULATION (MARCH 2023)

- Focuses on the in-person visit requirement
- No telemedicine registration - ?
- Introduces possibility of “qualifying telemedicine referral”
  - › Referring treater with DEA registration, after having in-person visit, can issue referral to prescriber
    - That prescriber can prescribe CS without an in-person visit
- To prescribe Schedule II
  - › Prior in-person visit
  - › OR qualifying telemedicine referral

# DEA *PROPOSED* REGULATION (MARCH 2023)

- To prescribe non-narcotic Schedule III-V:
  - › Can do a one-time 30 day prescription without in-person visit
  - › After that, needs a medical evaluation – 2 options:
    - Prescriber participates remotely in audio-visual meeting with the non-prescribing DEA registered practitioners seeing patient in-person, OR
    - Qualifying telemedicine referral
- Other pieces proposed
  - › Specifics for additional notations on prescription
  - › Etc.
- Separate regulation for prescribing buprenorphine

# DEA REGS

- May 3, 2023 – DEA says final regulation will not be done before the end of PHE
  - › Temporary extension of PHE waivers for prescribing CS coming
    - Waiving requirement to have one in-person visit prior to prescribing controlled substances, and
    - Waiving requirement to have DEA registration in patient's state, if different from prescriber's state
  - › Initially extended until at least November 11, 2023

# DEA REGS

- May 9, 2023 – DEA issued a temporary extension of PHE waivers for prescribing CS
  - › Until November 11, 2023
    - If patient and prescriber have established treatment relationship by November 11, 2023, same waivers continue until November 11, 2024
    - If treatment relationship is established after November 11, 2023, these waivers are not available



# DEA Hosts Public Listening Sessions on Telemedicine Regulations

## MEDIA ADVISORY - UPDATED

**WASHINGTON** – The Drug Enforcement Administration will host public listening sessions to receive comments from healthcare practitioners, experts, advocates, patients, and other members of the public to inform DEA's regulations on prescribing controlled substances via telemedicine.

The listening sessions will be held in person and livestreamed with remote participation available.

**WHAT:** Public Listening Sessions on Telemedicine Regulations

**WHO:** Open to the public

**WHEN:** September 12-13, 2023

**WHERE:** DEA Headquarters  
700 Army Navy Drive  
Arlington, Va. 22202

**Note: Registration for members of the public to attend in person or make oral presentations has now closed. The event will be livestreamed and publicly available.**

**FOR NEWS MEDIA:** News media wishing to attend in person must RSVP to [DEA.Public.Affairs@dea.gov](mailto:DEA.Public.Affairs@dea.gov) by 5 p.m. on September 11, 2023. Members of the media should arrive no later than 8 a.m. on September 12 and 13 for setup.

For more information, visit [Federal Register: Practice of Telemedicine: Listening Sessions](#).

<https://www.dea.gov/press-releases/2023/08/07/dea-hosts-public-listening-sessions-telemedicine-regulations>



You may recall that in response to the DEA's Proposed Rule on prescribing controlled substances via telemedicine from March, so many comments were filed that the DEA:

- Announced that the PHE-related telemedicine flexibilities for prescribing controlled substances would continue to be in effect, at least until November 2023. These flexibilities included:
  - Temporary waiver of the requirement to have an in-person visit prior to prescribing controlled substances
  - Temporary waiver of the requirement to have a DEA registration in the patient's state, in addition to the psychiatrist's state (if different) to prescribe controlled substances
- And, in an unprecedented move, held two days of listening sessions last month to try to “get the final rule right”
  - And announced that the Proposed Rule from March would be re-done, and there would be a new Proposed Rule issued, which could be commented on prior to the Final Rule being issued

On Friday, the [DEA announced](#):

- These federal telemedicine flexibilities for prescribing controlled substances will continue until December 31, 2024
- There is no requirement to have established a telemedicine relationship prior to November 11, 2023, to prescribe controlled substances without an in-person visit through December 31, 2024
  - Unlike the first temporary extension, you can establish a treatment relationship after November 11, 2023 and still not need an in-person visit through December 31, 2024

The new Rule with the second temporary extension of telemedicine flexibilities for prescribing controlled substances can be viewed [here](#).

As always, there could be state law in effect requiring an in-person visit related to prescribing to controlled substances; in those

# WHAT WE DO NOT KNOW

WE DO NOT KNOW ANYTHING ABOUT THE  
DEA'S FINAL RULE ON PRESCRIBING  
CONTROLLED SUBSTANCES VIA  
TELEMEDICINE

# FINAL DEA REGULATION

- What will NEW PROPOSED REGULATION say?
- What will the final regulation say?
  - Options for in-person visit requirement?
  - DEA registration needed in patient's state, if different?
- Is the DEA not going to do the telemedicine registration??
- When will it be issued?



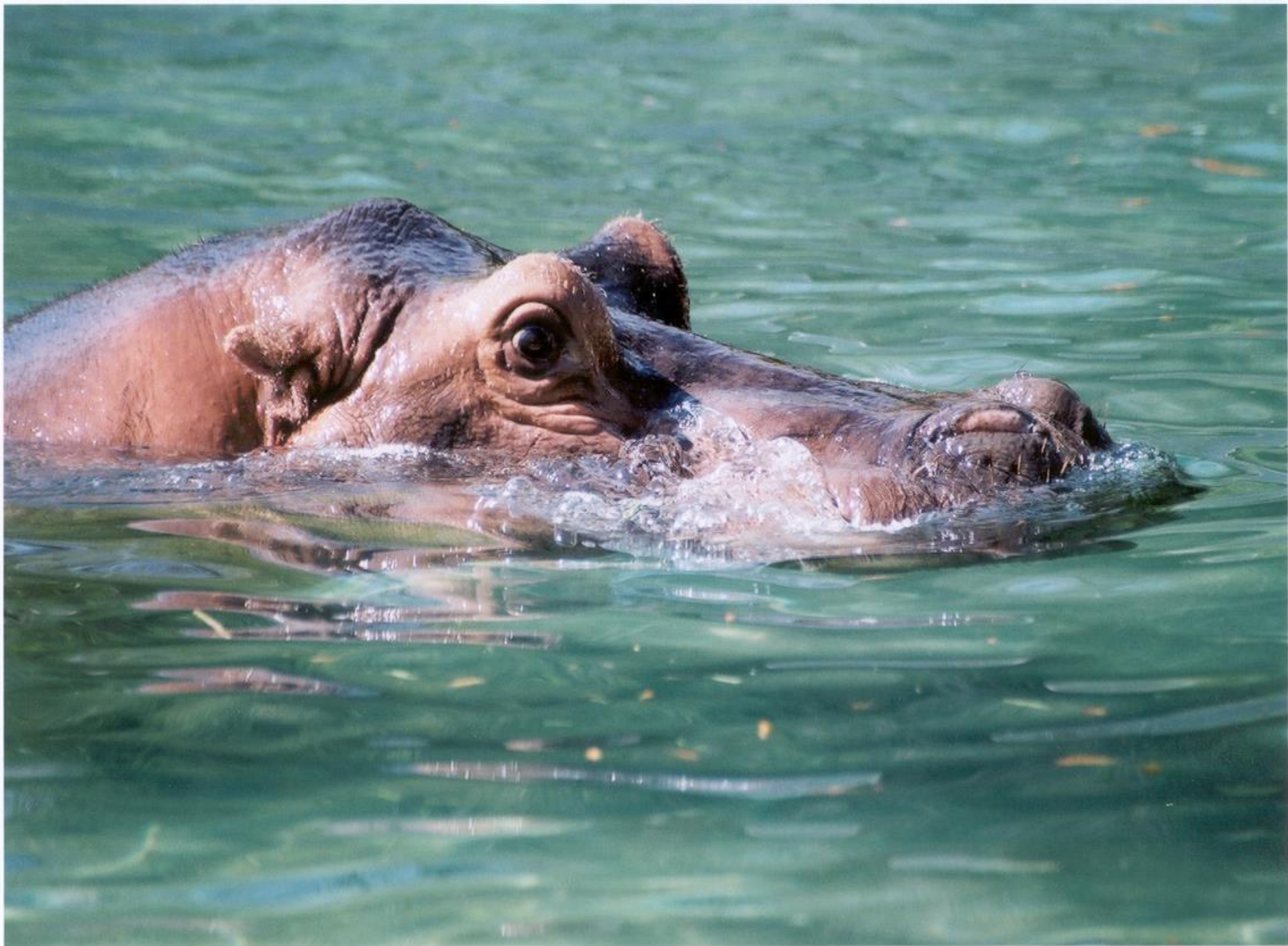
# WHAT WE KNOW

WE KNOW IN-PERSON VISITS  
MAY BE REQUIRED

# IN-PERSON VISIT REQUIREMENTS

- Federal requirement in future?
- State requirements
  - Controlled substances
  - Unrelated to controlled substances
- Payor requirements
- Clinical necessity





Covered health care providers that seek additional privacy protections for telehealth while using video communication products should provide such services through technology vendors that are HIPAA compliant and will enter into HIPAA business associate agreements (BAAs) in connection with the provision of their video communication products. The list below includes some vendors that represent that they provide HIPAA-compliant video communication products and that they will enter into a HIPAA BAA.

- Skype for Business / Microsoft Teams
- Updox
- VSee
- Zoom for Healthcare
- Doxy.me
- Google G Suite Hangouts Meet
- Cisco Webex Meetings / Webex Teams
- Amazon Chime
- GoToMeeting
- Spruce Health Care Messenger

# TELEPSYCH RESOURCES

- PRMS articles
  - Regulatory Fact Sheet
  - Treating Out-of-State College Students
  - 10 Things about Telepsychiatry
- PRMS website for updates
  - [www.prms.com/telepsych](http://www.prms.com/telepsych)

# AGENDA

- Introduction
- Technology
  - Telepsychiatry
  - EHRs
  - Social media
- Psychopharmacology
- 10 things about....

# EHR & DOCUMENTATION

Understand that the fact that the **EHR can create** documentation addressing the coding requirements for the highest code does not mean it is appropriate to bill the highest code

**Medical necessity** is the key to accurate coding, *even if a coding tool suggests a higher level of service*

# DOCUMENTATION “SHORT CUTS”

## Other ways to automate documentation:

- Templates
- Pre-populated fields
- Default data
- Documenting by exception
- Etc.

# DOCUMENTATION

From the NC Medical Board Position Statement on *Medical Record Documentation*:

“The Board recognizes and encourages the trend towards the use of electronic medical records (EMR). However, the Board cautions against relying upon software that pre-populates particular fields in the EMR without updating those fields in order to create a medical record that accurately reflects the elements delineated in the Position Statement.”

# DOCUMENTATION “SHORT CUTS”

## Automated documentation:

- Automated entry ≠ documented
- Unable to distinguish between data entered by clinician and system-entered data
- Documentation must be specific to the patient and to the services provided
- Clinicians are responsible for the accuracy of documentation



# EHR AND PATIENT SAFETY

## Potential Problems

- “Box checking” may eliminate clinically necessary information from the narrative
- Copy and paste may perpetuate error
  - › New information may be difficult to discern – it all looks the same
- Too much information may cause data to be missed

# EHR AND PATIENT SAFETY

## Potential Problems

- May be difficult to correct or amend record
  - › Changes may not be adjacent to the old
- Templates may not actually reflect what occurred during treatment
  - › A large number of identical notes will suggest provider wasn't thorough
  - › If too detailed, may appear invalid

# EHR'S AND LIABILITY

## Clinician Liability

- Expert witness
  - › Relies, to a great degree, on clinical record
- Professional Judgment Rule
  - › Courts will give great deference to treating provider IF there is something to base that deference on
    - Contemporaneous documentation
- Templates
  - › All records look the same
  - › Defendant provider loses credibility

# EHRs AND LIABILITY

## Clinician Liability

- Metadata
  - › Keeps track of everything user does, and how long it takes to do it
  - › Is discoverable
- Printed record
  - › EHRs do not look the same on paper
  - › EHRs may not contain all information in EHR

# EHR AND LIABILITY

## Clinician Liability

- Be very careful when documenting in the EHR
  - › Take your time and see what actual documentation is created
- Review the entry before closing it
- “The chart you are documenting may be the one you will be called on to defend on the witness stand.”

*Avoid the Dark Side of EHR Documentation, AAPC Coding Edge, Feb. 2011*

# TAKE AWAY POINT

Consider taking the following steps related to EHR documentation:

- Ensure templates used are appropriate for the specific patient
- Disable the cut and paste function
  - › If you allow this function, require author identification
- Do not allow pre-populated fields
- Do not allow auto population
- Include space for free-form text
- Periodically print out a record and review
  - › Any technical glitches?
  - › Would it pass a billing audit?
  - › Would a subsequent treater or an expert witness understand what you did and why?

# EHR - RESOURCES

- PRMS articles:
  - › EHR Contracts
  - › 10 Things about EHR Documentation
- ICNS article on EHR documentation
  - › [EHR Documentation: How to Keep Your Patients Safe, Keep Your Hard-Earned Money, and Stay Out of Court](#)

# AI IN PSYCHIATRIC PRACTICE

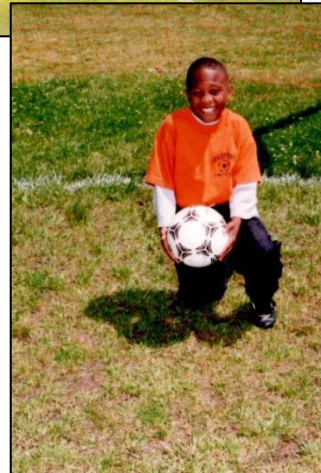
- Do not RELY on artificial intelligence
- AI should only supplement your decision-making
  - › NOT replace it
  - › “Augmented intelligence”
- Be transparent with patients
  - › May need consent
- Need to make AI’s role clear
- AI can hallucinate!
- Check with your professional liability insurance carrier for guidelines



# AGENDA

- Introduction
- Technology
  - › Telepsychiatry
  - › EHRs
  - › **Social media**
- Psychopharmacology
- 10 things about....

# JUSTIN POPE, JD





WELL, IF YOU FOLLOWED ME ON TWITTER, YOU'D ALREADY KNOW YOUR DIAGNOSIS.

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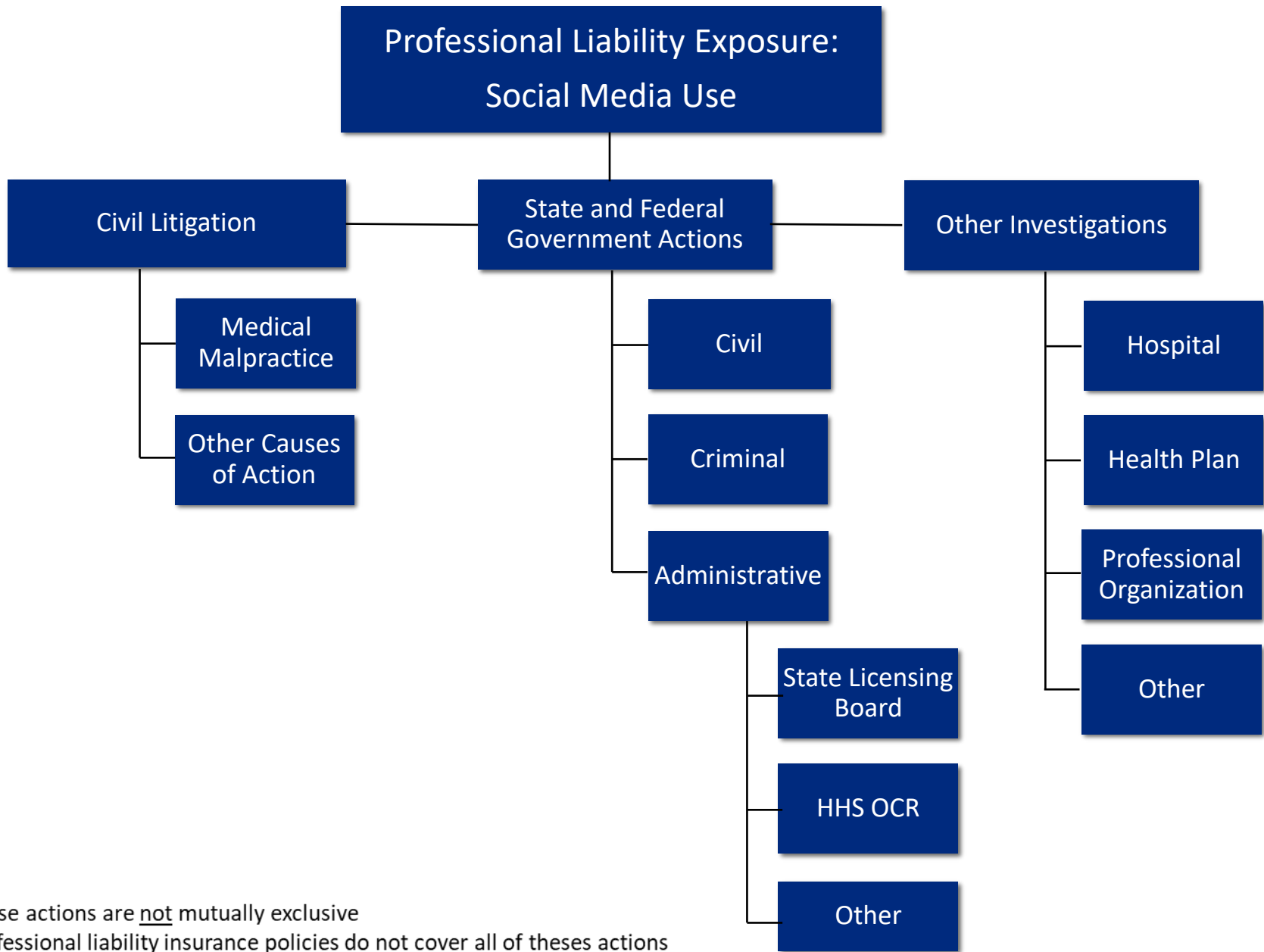
# WHERE TO START?



# COMMON PITFALLS

- Boundary violations
- Disclosure of PHI
- Inadvertent creation of treatment relationship
- Unlicensed practice of medicine
- Unprofessional conduct
- Vicarious liability

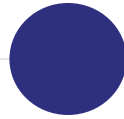
**Technology Does Not Change The Rules!**



Notes:

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

# **RISK OF MALPRACTICE LAWSUITS**





# Lawsuits allege dancing doctor was negligent



By [Kaylee Hartung](#), CNN

🕒 4 minute read · Published 1:04 PM EDT, Fri May 25, 2018



🗨️ Video Ad Feedback

'Dancing doctor' faces malpractice lawsuits

03:31 - Source: [HLN](#)

**(CNN)** — With a scalpel in her hand, Dr. Windell Boutte cuts into a patient's abdomen, in sync with the beat of O.T. Genasis' song "Cut it." She sings along.

LOCAL NEWS >

## Woman Sues Northwestern Medicine After Her Medical Information Was Posted On Twitter



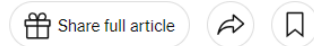
March 18, 2019 / 7:17 PM CDT / CBS Chicago



**CHICAGO (CBS)** – A woman at the center of a lawsuit said Northwestern Medicine Regional Medical Group did not inform her of a privacy breach of her medical records until she called after seeing the records posted on social media.

<https://www.cbsnews.com/chicago/news/northwestern-medicine-medical-information-twitter-privacy-breach/>

## *A blogger is unmasked in court - case closed*



May 31, 2007

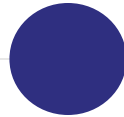
**BOSTON** — It was a Perry Mason moment updated for the Internet age.

As an Ivy League-educated pediatrician, Robert Lindeman, sat on the stand in Suffolk Superior Court in Massachusetts this month, defending himself in a malpractice suit involving the death of a 12-year-old patient, the opposing counsel startled him with a question.

Was Lindeman Flea?

Flea, jurors in the case didn't know, was the screen name for a blogger who had written often and at length about a trial remarkably similar to the one that was going on in the courtroom that day.

# RISK OF REGULATORY INVESTIGATION



Your State Attorney General

NEWS

## 'Dancing Doctor' to Pay \$190K to Settle State Claims of Unfair Business Practices

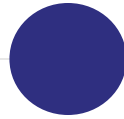
Dr. Windell Davis-Boutte was accused of claiming medical qualifications she did not hold, according to the consent judgment.

August 14, 2019 at 02:06 PM

Cosmetic surgeon Windell Davis-Boutte, aka the “dancing doctor”—whose videos of herself and her staff dancing, rapping and groping sedated patients undergoing procedures went viral—has agreed to pay \$190,000 to settle claims with the office of Attorney General Chris Carr that she violated the Georgia Fair Business Practices Act.

Under the terms of the [consent agreement](#), 38 patients of Davis-Boutte’s clinics—Premiere Dermatology & Surgery, Laser & Boutique and Boutte Contour Surgery & Dermatology—will have six months to file claims for restitution for services they paid for but never received and for which they were not reimbursed.

# RISK OF REGULATORY INVESTIGATION



Your Licensing Board

# LICENSING BOARD SANCTIONS & DISCIPLINARY FINDINGS

**Physicians may be disciplined for online behaviors such as:**

- Inappropriate communication with patients
- Use of the internet for unprofessional behavior
- Misrepresentation of credentials
- Violations of patient confidentiality
- Failure to reveal conflicts of interest
- Derogatory remarks regarding a patient
- Depiction of intoxication

**STATE MEDICAL BOARD INVESTIGATION OF PHYSICIANS' ONLINE ACTIVITIES**

Hypothetical Physician Online Activity	Percentage of Boards responding "likely" or "very likely" to investigate		
	>75%	50% - 75%	<50%
Citing misleading information about clinical outcomes	81% (39/48)		
Using patient images without consent	79% (38/48)		
Misrepresenting credentials	77% (37/48)		
Inappropriately contacting patients	77% (37/48)		
Depicting alcohol intoxication		73% (35/48)	
Violating patient confidentiality		65% (31/48)	
Using discriminatory speech		60% (29/48)	
Using derogatory speech toward patients			46% (29/48)
Showing alcohol use without intoxication			40% (19/48)
Providing clinical narratives without violation of confidentiality			16% (7/48)

Source: [Greysen SR et al., Online Professionalism Investigations by State Medical Boards: First, Do No Harm. Ann Intern Med. 15 Jan 2013;158\(2\):124-130](#)



# Resources & Information

Resources & Information  
 Overview

## Professional Resources

[Online Services](#)

[Laws, Rules and Position Statements](#)

[Special Topics](#)

### Publications

- [Forum Newsletter](#)
  - [Articles](#)
  - [Notices](#)
- [Disciplinary Reports](#)
- [Annual Reports](#)
- [Glossary/Disciplinary Definitions](#)
- [Brochures](#)

[NC PHP](#)

[Look Up a Licensee](#)

**Jun 11 2019**

## Clinicians on social media: no taking off the white coat

 Jun 11, 2019 |  Barbara E. Walker, DO |  Newsletter: [May-June 2019 Forum](#) |  Categories: [President's Message](#) |  0 comments |  [Print Friendly Version](#) |  [Share this item](#)



It was probably inevitable.

Social media is so entwined with every aspect of our lives that it is becoming an active driver of Medical Board disciplinary work.

One recent case involved the posting of an operating room photo of a licensee and members of the surgical team, a draped patient's naked abdomen visible in the background. The comments on the post included irreverent remarks by the licensee that would have been embarrassing- perhaps humiliating- to the unidentified patient.

Another case stemmed from a negative online review one licensee wrote disparaging a colleague's competence after a contentious interaction over a mutual patient. In responding to the Board's inquiry, the licensee who wrote the review refused to delete it, evidently seeing nothing wrong with medical professionals airing dirty laundry via Facebook recommendation.



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LOUISIANA STATE BOARD  
OF MEDICAL EXAMINERS

**STATEMENT OF POSITION**

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THE USE OF SOCIAL MEDIA BY PHYSICIANS AND OTHER HEALTHCARE PROVIDERS\*

---

[August 2015]

**BACKGROUND.** The Louisiana State Board of Medical Examiners (the "Board") has received complaints and other information from the public in which it is alleged that physicians have misused social media, primarily in the areas of the patient-physician boundary, patient privacy, and the inappropriate representation of the physician and medical establishment through posts, photos, or videos.

In response to these complaints, the Board has deemed that guidance to physicians regarding social media is warranted. In preparing this report, the Board has performed an analysis concerning recommendations published by professional and regulating agencies that specifically address the use of this technology and medical professionalism.

**STATEMENT OF POSITION.** By declaring the following Statement, the Board intends to: (i) protect the public and ensure quality of health care in Louisiana; and (ii) inform Louisiana physicians of necessary precautionary measures when having an online presence.

## PREVIOUS POSITION FROM MSBML (2021)

“...Physicians have an ethical obligation to ensure that medical information they provide in a media environment is accurate, inclusive of known risks and benefits, commensurate with their medical expertise, and based on valid scientific evidence and insight gained from professional experience. Further, it is strongly recommended that in the use of social media, physicians should separate their personal and professional content online. Physicians must understand that actions online and content posted can affect their reputation, have consequences for their medical careers, and undermine public trust in the medical profession.”

[https://www.msbml.ms.gov/sites/default/files/Rules\\_Laws\\_Policies/9-2021Policies.pdf](https://www.msbml.ms.gov/sites/default/files/Rules_Laws_Policies/9-2021Policies.pdf)



## **Social Media and Electronic Communications**

*Report and Recommendations of the FSMB Ethics and Professionalism Committee*

*Adopted as policy by the Federation of State Medical Boards April 2019*

### **Introduction and Charge:**

In April 2018, Federation of State Medical Boards (FSMB) Chair, Patricia King, MD, PhD, tasked the FSMB's Ethics and Professionalism Committee (the Committee) with providing updated guidance on use of social media and electronic communications in medical practice and by state medical boards. Specifically, the Committee was charged with:

1. Evaluating current and emerging social media and electronic platforms for communication between practitioners and practitioners with patients, as well as communication in educational settings (students and residents), including blogs, twitter, websites, email, EHR patient portals, and others,
2. Reviewing current state medical board actions and concerns regarding social media, electronic communication, and professional conduct, and
3. Reviewing the FSMB 2012 policy, "Model Guidelines for the Appropriate Use of Social Media and Social Networking," and revise, amend or replace with updated recommendations for best practice in the professional use of electronic and social media communication.

# AMA ETHICS OPINION 2.3.2: PROFESSIONALISM IN THE USE OF SOCIAL MEDIA

- Maintain patient privacy and confidentiality
- Refrain from posting identifiable patient information
- Use privacy settings to safeguard personal information
- Recognize that privacy settings are not absolute and that once on the internet, content is likely there permanently.
- Routinely monitor your online presence.
- Separate personal and professional content online
- Maintain appropriate boundaries with the patient – physician relationship, just as in any other context

**US**

Crime + Justice

Energy + Environment

Extreme Weather

Space + Science

# ‘Dancing Doctor’ agrees to two-and-a-half-year suspension of medical license, records show

By Ralph Ellis and Jamie Lynch, CNN

© 2 minute read · Updated 6:29 AM EDT, Sun July 1, 2018



**(CNN)** — “The Dancing Doctor” has agreed to give up her medical license for at least two and a half years, according to an agreement filed Friday with the Georgia Composite Medical Board.

The consent order signed by Windell Boutte, a board-certified dermatologist, says that her license to practice medicine in Georgia is indefinitely suspended, but after two and a half years she can petition to have the suspension lifted.

She cannot use the title “doctor” or engage in the practice of medicine during her suspension, the document says, and will drop her own court case in which she seeks a temporary restraining order.

The publicist team for Boutte issued this statement: “Windell Davis-Boutte respects the process and has voluntarily accepted the consent order for suspension. She is hopeful that the suspension will be lifted and she is able to practice Medicine at some point in the near future.”

# Doc Who Livestreamed Surgeries on TikTok Loses License

— Katharine Roxanne Grawe, MD, will also have to pay a fine of \$4,500

by [Jennifer Henderson](#), Enterprise & Investigative Writer, MedPage Today July 13, 2023

---



An Ohio plastic surgeon had her medical license permanently revoked this week following concerns about her livestreams of procedures on TikTok, and about reports of patient complications.





# STATE OF IOWA

KIM REYNOLDS, GOVERNOR  
ADAM GREGG, LT. GOVERNOR

IOWA BOARD OF MEDICINE  
KENT NEBEL, J.D., EXECUTIVE DIRECTOR

## PRESS RELEASE IOWA BOARD OF MEDICINE (November 23, 2020)

Recently, the Iowa Board of Medicine took the following action:

[Dara Parvin, M.D.](#), a 54-year-old Iowa-licensed physician who formerly practiced orthopedic surgery in Dubuque, Iowa, entered into a combined Statement of Charges and Settlement Agreement with the Board on November 19, 2020. The Board alleged that Dr. Parvin engaged in unprofessional conduct in violation of the laws and rules governing the practice of medicine in Iowa. The Board alleged that following the overconsumption of alcohol, Dr. Parvin sent suggestive social media messages and made unwanted advances toward a female patient who he had briefly seen in his office several years prior and referred on to another specialist. The contact was made outside of work hours and outside of a work setting. The Board alleged that Dr. Parvin sent suggestive text messages and social media messages to, and made inappropriate comments and unwanted advances toward, a colleague. The Board also alleged that Dr. Parvin sent suggestive text messages and social media messages to, and made inappropriate comments and unwanted advances toward, co-workers. Under the terms of the November 19, 2020, combined Statement of Charges and Settlement Agreement, the Board issued Dr. Parvin a Citation and Warning and ordered him to pay a \$1,500 civil penalty. The Board also prohibited Dr. Parvin from using social media to contact any patient outside of the physician-patient relationship or to make unwanted advances toward colleagues or co-workers. The Board also placed Dr. Parvin on probation for a period of two years subject to professional boundaries counseling and Board monitoring.



# RISK OF REGULATORY INVESTIGATION



HHS Office of Civil Rights – HIPAA



## Health Information Privacy



HIPAA for Individuals

Filing a Complaint

HIPAA for Professionals

Newsroom

HHS > HIPAA Home > For Professionals > HIPAA Compliance and Enforcement > Resolution Agreements > Physical therapy provider settles violations

HIPAA for Professionals
Regulatory Initiatives
Privacy +
Security +
Breach Notification +
Compliance & Enforcement +
Special Topics +
Patient Safety +
Covered Entities & Business Associates +
Training & Resources
FAQs for Professionals
Other Administrative Simplification Rules



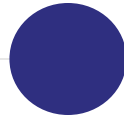
# Physical therapy provider settles violations that it impermissibly disclosed patient information

Complete P.T., Pool & Land Physical Therapy, Inc. has agreed to settle violations of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rules with the U.S. Department of Health and Human Services Office for Civil Rights (OCR). Complete P.T. is a physical therapy practice located in the Los Angeles area. The settlement agreement is an admission of civil liability by Complete P.T., requiring payment of \$25,000, adoption and implementation of a corrective action plan, and annual reporting of compliance efforts for a one year period.

On August 8, 2012, OCR received a complaint alleging that Complete P.T. had impermissibly disclosed numerous individuals' protected health information (PHI), when it posted patient testimonials, including full names and full face photographic images, to its website without obtaining valid, HIPAA-compliant authorizations. OCR's investigation revealed that Complete P.T.:

- Failed to reasonably safeguard PHI;
- Impermissibly disclosed PHI without an authorization; and

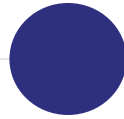
# **RISK OF LOSING HOSPITAL PRIVILEGES OR EMPLOYMENT**



# Do not do what “Dr. Killpatient” did!

investigation in this matter reveals that he was employed at Englewood Hospital until the events reflected herein. The summary suspension of his privileges was based on conduct evidenced by Dr. K\_\_\_\_\_'s active participation in his Twitter account. The account was opened in 2009 using the handle "@erstories" and later, when the doctor grew concerned that his identity was known to his co-workers and Englewood Hospital, under the new handle of "@talesfromtheer" and nicknamed "Dr.Killpatient"<sup>1</sup>. At the time of his suspension, Dr. K\_\_\_\_\_  
had approximately 2600 followers, at least one of whom was a coworker at Englewood Hospital<sup>2</sup>.

# **RISK MANAGEMENT ADVICE**



# BEFORE USING SOCIAL MEDIA...

- Understand the platform, its audience, and its various functionalities.
- Review any relevant social media requirements or policy guidance from your regulators, employers, and professional organizations.
- Ensure personal use will be kept separate from private use.
- Review privacy settings for both professional and personal accounts.

# WHEN POSTING ON SOCIAL MEDIA...

- Pause before posting!
  - › Are you okay with your post being seen by:
    - Your employer
    - Your employees
    - An ethics committee
    - Your licensing board(s)
    - An attorney representing a plaintiff suing you
- Protect confidentiality
  - › More to de-identifying than changing names
  - › Consider obtaining patient consent
- Don't count on anonymity
  - › Assume intrepid patients will uncover posts
  - › May be used against you/discovery in litigation
  - › Posts will reflect on you and your profession

# WHEN POSTING ON SOCIAL MEDIA...

- Remember that social media platforms are largely public forums.
  - › Don't slander or vent about patients/workplaces.
  - › You will be responsible for your content and it's accuracy
  - › Comments cannot be controlled
  - › Comply with any relevant advertising requirements and respect intellectual property
  - › Make it clear that posts are not is intended as medical advice and do not establish a treatment relationship.



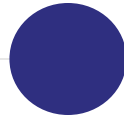
# LISTSERVS

- Though private, info may be forwarded
- May be discoverable
- Maintain confidentiality
- Frame discussion as informal consult vs. treatment advice
- May appear as “supervision” to non-physician

# ONLINE PHYSICIAN COMMUNITIES

- Online version of curbside consult
- Physician only
- Collaborate on difficult cases
- Share observations/information
- Communications will create a permanent record
  - › Discoverable
- MD/JD may be lurking
- Potential for privacy breach
  - › Minimum info necessary
  - › Consider direct email

# NEGATIVE ONLINE REVIEWS



## Attorney General Cuomo Secures Settlement With Plastic Surgery Franchise That Flooded Internet With False Positive Reviews

NEW YORK, N.Y. (July 14, 2009) - Attorney General Andrew M. Cuomo today announced a settlement with cosmetic surgery outfit Lifestyle Lift over the publishing of fake consumer reviews on the Internet.

Under the settlement, Lifestyle Lift will stop publishing anonymous positive reviews about the company to Internet message boards and other Web sites, and will pay \$300,000 in penalties and costs to the State of New York. The case is believed to be the first in the nation aimed at combating "astroturfing," a growing problem on the Internet.

Lifestyle Lift employees published positive reviews and comments about the company to trick Web-browsing consumers into believing that satisfied customers were posting their own stories. These tactics constitute deceptive commercial practices, false advertising, and fraudulent and illegal conduct under New York and federal consumer protection law. The settlement marks a strike against the growing practice of "astroturfing," in which employees pose as independent consumers to post positive reviews and commentary to Web sites and Internet message boards about their own company.

"This company's attempt to generate business by duping consumers was cynical, manipulative, and illegal," said Attorney General Cuomo. "My office has and will continue to be on the forefront in protecting consumers against emerging fraud and deception, including 'astroturfing,' on the Internet."

Lifestyle Lift has more than 40 locations across the U.S., including Manhattan, Long Island and Syracuse. The company engaged in a concerted effort to bombard Internet message boards with positive stories about themselves. Lifestyle Lift's president believed that negative Internet postings had significantly hurt the company's reputation and thought the success of the company hinged on controlling messages posted online. Company employees were directed to create accounts with various Internet message boards and pose as satisfied customers of Lifestyle Lift. Employees also attacked legitimate message board posters who criticized Lifestyle Lift and tried to get those posts removed from message boards.

Internal emails discovered by Attorney General Cuomo's investigation show that Lifestyle Lift employees were given specific instructions to engage in this illegal activity. One e-mail to

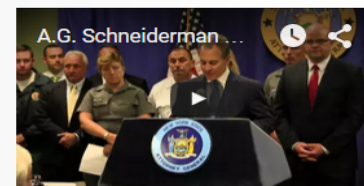
New York City Press Office: (212) 416-8060

Albany Press Office: (518) 776-2427

[nyag.pressoffice@ag.ny.gov](mailto:nyag.pressoffice@ag.ny.gov)



### A.G. Schneiderman Announces Indictments Against 20 Capital Area Residents, Including Former Watervliet Police Officer, In "Operation Trojan Horse" Drug Bust



### A.G. Schneiderman Cracks Down On Illegal Toy Guns Sales, Announces Settlements With Amazon, Walmart And Other Major Retailers To Halt Sales Of Life-Like Imitation Guns In New York



# ENFORCEMENT EXAMPLE FROM OCR

## Private Practice Ceases Conditional of Compliance with the Privacy Rule

“A physician practice requested that patients sign an agreement entitled “Consent and Mutual Agreement to Maintain Privacy.” The agreement prohibited the patient from directly or indirectly publishing or airing commentary about the physician, his expertise, and/or treatment in exchange for the physician’s compliance with the Privacy Rule. A patient’s rights under the Privacy Rule are not contingent on the patient’s agreement with a covered entity. A covered entity’s obligation to comply with all requirements of the Privacy Rule cannot be conditioned on the patient’s silence. OCR required the covered entity to cease using the patient agreement that conditioned the entity’s compliance with the Privacy Rule. Additionally, OCR required the covered entity to revise its Notice of Privacy Practices.”



## Health Information Privacy



- HIPAA for Individuals
- Filing a Complaint
- HIPAA for Professionals
- Newsroom

HHS > HIPAA Home > For Professionals > HIPAA Compliance and Enforcement > Resolution Agreements > Dental Practice Pays \$10,000 to Settle Social Me...

- HIPAA for Professionals
- Regulatory Initiatives
- Privacy +
- Security +
- Breach Notification +
- Compliance & Enforcement +
- Special Topics +
- Patient Safety +
- Covered Entities & Business Associates +
- Training & Resources
- FAQs for Professionals
- Other Administrative Simplification



# Dental Practice Pays \$10,000 to Settle Social Media Disclosures of Patients' Protected Health Information

Elite Dental Associates, Dallas ("Elite") has agreed to pay \$10,000 the Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services and to adopt a corrective action plan to settle potential violations of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. Elite is a privately-owned dental practice located in Dallas, Texas, providing general, implant, and cosmetic dentistry.

- [Read the HHS Press Release](#)
- [Read the Resolution Agreement - PDF\\*](#)

\*People using assistive technology may not be able to fully access information in this file. For assistance, contact the HHS Office for Civil Rights at (800) 368-1019, TDD toll-free: (800) 537-7697, or by emailing [OCRMail@hhs.gov](mailto:OCRMail@hhs.gov).



Health Information Privacy



- HIPAA for Individuals
- Filing a Complaint
- HIPAA for Professionals
- Newsroom

HHS > HIPAA Home > For Professionals > HIPAA Compliance and Enforcement > Resolution Agreements > HHS Office for Civil Rights Reaches Agreement wi...

- HIPAA for Professionals
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- Patient Safety +
- Covered Entities & Business Associates +
- Training & Resources
- FAQs for Professionals
- Other Administrative Simplification



## HHS Office for Civil Rights Reaches Agreement with Health Care Provider in New Jersey That Disclosed Patient Information in Response to Negative Online Reviews

OCR has announced a settlement with Manasa Health Center, LLC, a health care provider in New Jersey that provides adult and child psychiatric services. The settlement resolves a complaint received by OCR in April 2020, alleging that Manasa Health Center impermissibly disclosed the protected health information of a patient when the entity posted a response to the patient's negative online review. Following an OCR investigation, potential violations of the HIPAA Privacy Rule include impermissible disclosures of patient protected health information in response to negative online reviews, and failure to implement policies and procedures with respect to protected health information. Manasa Health Center paid \$30,000 to OCR and agreed to implement a corrective action plan to resolve these

## APA Resource Document

### Resource Document on Responding to Negative Online Reviews

Approved by the Joint Reference Committee, October 2019

"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*

#### Prepared by the APA Ethics Committee

The American Psychiatric Association (APA) Ethics Committee occasionally receives inquiries from members who are troubled by negative reviews about them or their practice posted online by patients or other individuals. This often creates a difficult dilemma for the psychiatrist who must respect the patient's voice but also desires to preserve the integrity of the psychiatrist's public image. This resource document is offered to provide guidance to psychiatrists regarding receipt of negative online reviews.

Many posted reviews contain only the opinions of patients (or other individuals) and, as such, are protected speech under the First Amendment of the U.S. Constitution, without exception. Most service providers receive a negative review at one time or another, and it is best not to overreact to a single such posting. If, however, a psychiatrist receives numerous negative reviews (and especially if the reviews repeat similar complaints), the psychiatrist would be well-advised to take time to reflect on the complaints in a thoughtful and constructive manner and to endeavor to make efforts to improve their approach to patients and/or treatment. The "physician-patient relationship is the cornerstone of psychiatric practice, and its goal is to promote patient health and well-being, embodying the key ethical considerations of respect for persons, fairness, and beneficence." *APA Commentary on Ethics in Practice*, Topic 3.1.1.



# NEGATIVE ONLINE REVIEWS

- Try to resolve issues with current patients
  - › Do not ask patient to remove post.
  - › Do not ask attorney to contact patient.
- Consider whether post violates review site's rules within its terms of use.
  - › Cannot confirm treatment with review site.
- Do not respond directly to a patient's post!
  - › Doing so would constitute a breach of confidentiality.
  - › May generally clarify your practices.
- May solicit feedback from other patients in a non-coercive way.

## TAKE AWAY POINTS

- Technology does not change duty to maintain boundaries and protect confidentiality
- Use privacy settings to limit access
- Do not post anything you would be uncomfortable having others see
- Do not respond directly to negative online reviews

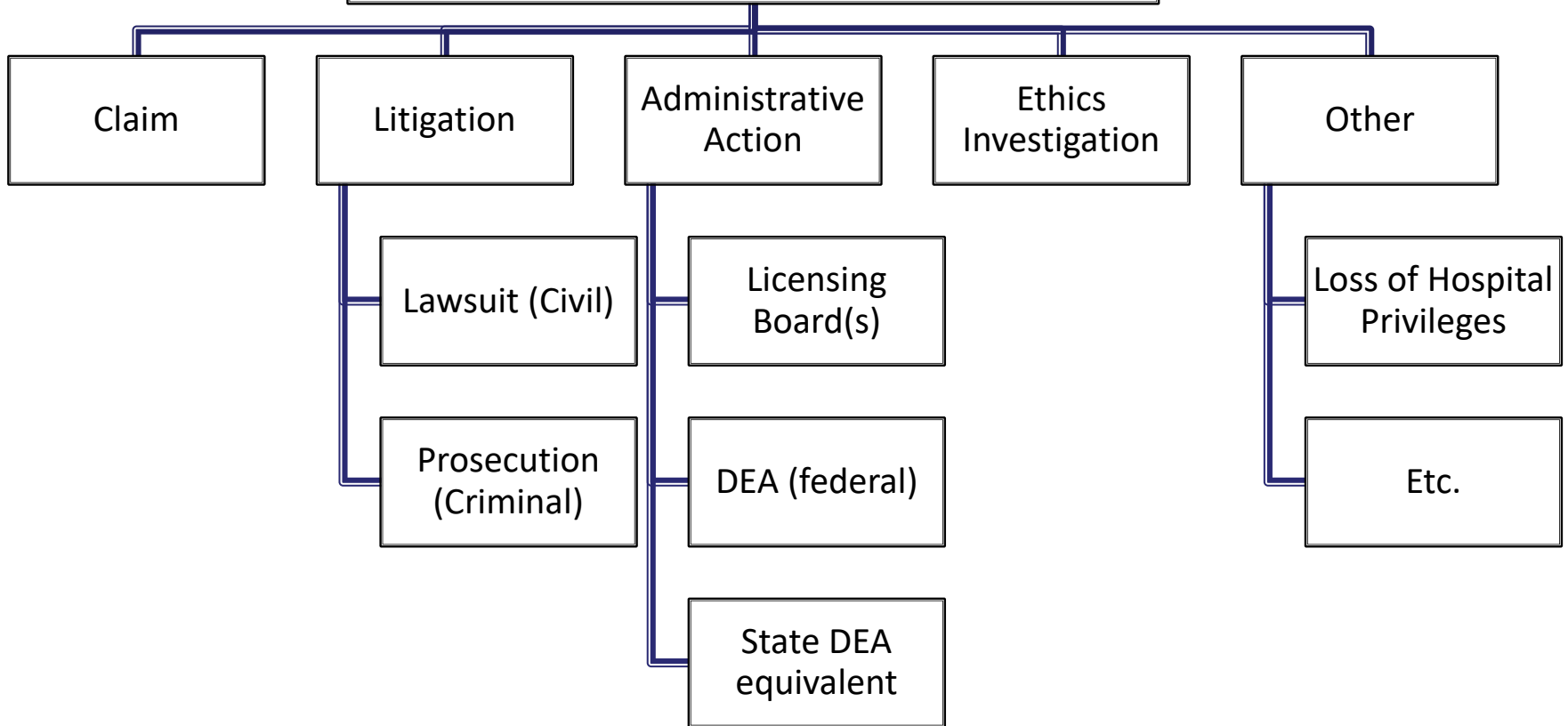
# SOCIAL MEDIA - RESOURCES

- PRMS articles:
  - › 10 Things about Social Media
  - › 10 Things about Online Reviews
- ICNS article:
  - › [What Can I Do about a Negative Online Review?](#)

# AGENDA

- Introduction
- Technology
  - › Telepsychiatry
  - › EHRs
  - › Social media
- **Psychopharmacology**
- 10 things about....

PROFESSIONAL LIABILITY EXPOSURE:  
PRESCRIBING CONTROLLED SUBSTANCES



# 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

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

# **CONTROLLED SUBSTANCE ACT: 21 USC 801-890**

DEA is responsible for ensuring that all controlled substance transactions take place within the closed system of distribution established by Congress.



# 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”

United States Department of Justice  
Drug Enforcement Administration  
Diversion Control Division

[www.DEAdiversion.usdoj.gov](http://www.DEAdiversion.usdoj.gov)



# Practitioner's Manual

## AN INFORMATIONAL OUTLINE OF THE CONTROLLED SUBSTANCES ACT

Revised 2023<sup>1</sup>

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<sup>1</sup> This manual replaces all previous editions of the Practitioner's Manual issued by the Drug Enforcement Administration, both hard copy and electronic.

[https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-071\)\(EO-DEA226\)\\_Practitioner's\\_Manual\\_\(final\).pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-071)(EO-DEA226)_Practitioner's_Manual_(final).pdf)

# ***U.S. V. ROSEN, 582 F2D 1032 (1978)***

“We are, however, able to glean from reported cases certain recurring concomitance of condemned behavior, examples of which include the following:

- 1) An inordinately large quantity of controlled substances was prescribed.
- 2) Large numbers of prescriptions were issued.
- 3) No physical examination was given.
- 4) The physician warned the patient to fill prescriptions at different drug stores.
- 5) The physician issued prescriptions to a patient known to be delivering the drugs to others.

# ***U.S. V. ROSEN, 582 F2D 1032 (1978)***

*(CONTINUED)*

- 6) The physician prescribed controlled drugs at intervals inconsistent with legitimate medical treatment.
- 7) The physician involved used street slang rather than medical terminology for the drugs prescribed.
- 8) There was no logical relationship between the drugs prescribed and treatment of the condition allegedly existing.
- 9) The physician wrote more than one prescription on occasions in order to spread them out.

# 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

# REMEMBER

*A valid prescription is done for a **legitimate medical purpose** by a prescriber acting in the **usual course of practice***

# THE RESPONSE: VARIOUS INITIATIVES

- State
  - Opioid task forces
  - Restrictions on opioid prescribing
  - Prescribing guidelines
  - Mandated use of PMPs
  - Lawsuits against Pharma
  - Enforcement
- Federal
  - Public Health Emergency declaration
  - Guidelines
  - CMS initiatives
  - Enforcement



# FEDERAL V. 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

## DOJ / DEA

- Primary agency charged with policing the issuance and dispensing of controlled substances
- Per CSA: must be a legitimate medical purpose and must be acting in usual course of practice
- Penalties: imprisonment, fines, loss of DEA license

# FEDERAL

## DEA VISITS

- CSA authorizes DEA to enter controlled premises and conduct periodic inspections

# 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

[http://www.acponline.org/about\\_acp/chapters/az/rivera-armando.pdf](http://www.acponline.org/about_acp/chapters/az/rivera-armando.pdf)

# FEDERAL

## DEA PROBLEM AREAS:

- 2) Diversion
- 3) Excessive / Unauthorized Prescribing
- 4) Internet Prescribing

[http://www.acponline.org/about\\_acp/chapters/az/rivera-armando.pdf](http://www.acponline.org/about_acp/chapters/az/rivera-armando.pdf)

# FEDERAL

## DEA SUGGESTIONS

### Document:

- Legitimate reason for prescribing
- Analysis of prior records
- Adequate history and physical examination
- History of drug abuse
- Supporting x-rays, etc.
- Continued re-evaluation of pain relief and function
- Treatment plan

# FEDERAL

## DEA SUGGESTIONS

### Document (*Continued*):

- Patient's compliance with meds and treatment
- Amount of controlled substances prescribed
- Amount used since last visit
- Amount of dosages remaining
- Amount of pain relief
- Improvement in function
- Evidence of abuse / diversion

# FEDERAL

## DEA SUGGESTIONS

- Patient contract
- Pill counts
- Surprise drug testing
- PMP
- Adhere to clinical guidelines

[http://www.acponline.org/about\\_acp/chapters/az/rivera-armando.pdf](http://www.acponline.org/about_acp/chapters/az/rivera-armando.pdf)



HEALTH TECH



# Cerebral under federal investigation for possible violations of controlled substances law

By Heather Landi · May 7, 2022 4:09pm

Cerebral

Behavioral Health

U.S. Department of Justice

subpoena



Cerebral is among a handful of virtual care startups that prescribe controlled substances without patients seeing a doctor in person. (Cerebral)

Mental health startup Cerebral said Saturday it is under investigation by the Department of Justice (DOJ) for "possible violations" of the Controlled Substances Act.

Cerebral Medical Group received a grand jury subpoena from the U.S. Attorney's Office for the Eastern District of New York on Friday evening, the company said in a statement. The

<https://fiercehealthcare.com/health-tech/cerebral-under-federal-investigation-possible-violation-controlled-substances-law>

# DEA Investigating ADHD Telehealth Provider Done

Agency probe concentrated in division that investigates potentially illicit use of legal drugs, documents show

By *Rolfe Winkler* [Follow](#)

Updated Sept. 16, 2022 8:04 pm ET



A federal law requires doctors to conduct at least one in-person appointment with a patient before prescribing them a controlled substance like Adderall. PHOTO: SHUTTERSTOCK

U.S. Drug Enforcement Administration agents have questioned people about telehealth company Done Global Inc.'s practices for prescribing controlled substances, according to documents reviewed by The Wall Street Journal and people familiar with the inquiries.

<https://www.wsj.com/articles/dea-investigating-adhd-telehealth-provider-done-11663239601>

# Walmart, CVS to halt filling prescriptions for controlled substances by Cerebral, Done

Reuters

May 26, 2022 7:12 PM EDT · Updated 2 years ago



[1/3] A Walmart sign is pictured at one of their stores in Mexico City, Mexico March 28, 2019. REUTERS/Edgard Garrido  
[Purchase Licensing Rights](#)



## Companies



Walmart Inc

Follow



CVS Health Corp

Follow

May 26 (Reuters) - Walmart Inc ([WMT.N](#)) and CVS Health Corp ([CVS.N](#)) said on Wednesday they would stop filling prescriptions for controlled substances issued by telehealth startups Cerebral Inc and Done Health.

Cerebral and Done are known for treating patients with ADHD, prescribing stimulants such as Adderall.

Walmart confirmed the move to Reuters and said the decision was made after an audit and compliance process.

CVS said it would not accept prescriptions for controlled substances issued by the startups effective May 26, as a result of a review it conducted on the telehealth firms and after it was "unable to resolve concerns we have with Cerebral and Done Health."

<https://www.reuters.com/business/healthcare-pharmaceuticals/walmart-cvs-halt-filling-prescriptions-controlled-substances-by-cerebral-done-2022-05-26/>

HEALTH

## CVS and Walgreens agree to pay \$10 billion to settle lawsuits linked to opioid sales

DECEMBER 13, 2022 · 7:22 AM ET

By Ayana Archie



CVS would pay nearly \$5 billion over 10 years, while Walgreens would pay \$5.7 billion over 15 years, in a settlement over their roles in the opioid crisis.

*Keith Srakocic/AP*

CVS and Walgreens have agreed to pay more than \$10 billion to several states in a settlement of lawsuits brought against them alleging their roles in the opioid crisis.

CVS would pay nearly \$5 billion over 10 years, while Walgreens would pay \$5.7 billion over 15 years, according to statements released by state attorneys general.

<https://www.npr.org/2022/12/13/1142416718/cvs-walgreens-opioid-crisis-settlement#:~:text=Health-.CVS%20and%20Walgreens%20agree%20to%20pay%20%2410%20billion.lawsuits%20linked%20to%20opioid%20sales&text=Keith%20Srakocic%2FAP-.CVS%20would%20pay%20nearly%20%245%20billion%20over%2010%20years%2C%20while.roles%20in%20the%20opioid%20crisis>

# Court Orders Maryland Pharmacy to Pay \$120,000 Penalty in Case Alleging Unlawful Opioid Distribution

Thursday, July 6, 2023

Share >

For Immediate Release

Office of Public Affairs

A federal court enjoined a Cumberland, Maryland, pharmacy and its owner and pharmacist from dispensing controlled substances, including opioids, without taking specific steps to help ensure the drugs will not be abused or diverted, and ordered them to pay a \$120,000 civil penalty.

The court's order, entered pursuant to a consent decree of permanent injunction, resolves a complaint filed by the United States on June 16 alleging that Beckman's Greene Street Pharmacy and its owner and pharmacist-in-charge, John A. Beckman, filled hundreds of prescriptions in violation of the Controlled Substances Act (CSA). The complaint alleges that the defendants ignored obvious "red flags" of drug abuse, drug diversion, and drug-seeking behavior. For example, according to the complaint, the defendants repeatedly filled prescriptions for dangerously large doses and high-risk combinations of controlled substances known to be sought by drug abusers and which significantly increase the risk of overdose. The complaint alleges that the defendants frequently filled prescriptions for an opioid known as buprenorphine in a form that did not include the abuse-deterrent component with which it is ordinary prescribed. The complaint further alleges that the defendants often dispensed controlled substances to patients who lived long distances from the pharmacy or who paid in cash despite the availability of insurance. According to the complaint, at least 10 patients died within 10 days of having controlled substance prescriptions filled at Beckman's Greene Street Pharmacy.

"Pharmacies and pharmacists have an obligation to prevent the illegal dispensing of controlled substances," said Principal Deputy Assistant Attorney General Brian M. Boynton, head of the Justice Department's Civil Division. "The department will work with its law enforcement partners to hold responsible those who dispense potentially dangerous prescription drugs in violation of the law."

<https://www.justice.gov/opa/pr/court-orders-maryland-pharmacy-pay-120000-penalty-case-alleging-unlawful-opioid-distribution>

# PHARMACY LIABILITY

- Based on “red flags” from DEA
  - › Including patients who travel long distances
- Results include:
  - › Pharmacies refusing to fill prescriptions from out-of-state prescribers
  - › Adverse impact on telemedicine

# Telehealth Industry Pushes DEA on 'Red Flags' for Prescriptions

EXCLUSIVE



Ganny Belloni ✉ ✕

- Agency urged to clarify rules on telehealth dispensing
- DEA asked to avoid 'red flags' for out-of-state prescriptions

Telehealth industry leaders are putting pressure on the Drug Enforcement Administration to guide pharmacists on how to safely dispense controlled substances without limiting access for the drugs to patients who need them.

In a [letter](#) to the DEA released Wednesday, a consortium of online health-care companies, trade groups, and policy organizations urged the agency to provide explicit guidance informing pharmacies that the “geography of a prescriber in relation to the patient or the pharmacy should not be a ‘red flag’ when a prescription is a result of a telehealth visit.”

Currently, pharmacists who notice prescriptions filed by out-of-state telehealth providers have the [discretion](#) under the Controlled Substances Act to block treatments they deem too risky to fulfill.

While red flags are not explicitly outlined in statute or regulations, in the aftermath of the widespread over-dispensing that contributed to the opioid crisis, pharmacists have been directed to identify red flags as part of their due diligence to ensure that prescriptions are legitimate, the letter said.

These red flags often [include](#) behaviors such as writing significantly more prescriptions than other practitioners in a particular area, returning too frequently for refills, or presenting prescriptions in the name of other people.

“If pharmacists are reticent to fulfill these prescriptions of controlled substances because the provider isn't physically geographically proximate to the patient, the patient is out in the cold,” Kyle Zebley, senior vice president of public policy at the American Telemedicine Association, said in an interview.

## Documents

[Letter to DEA](#)

## Related Stories

[Telehealth Boosters, Lawmakers Aim To Lock In Policy Changes](#)

December 29, 2023, 5:05 AM EST

[Telehealth Industry Applauds DEA's Online Prescribing Extension](#)

Oct. 6, 2023, 5:20 PM EDT

[Telehealth Leaders Urge DEA To Adopt Easier Prescribing Policies](#)

Sept. 12, 2023, 5:35 PM EDT

Q Search by **Law Firm**

[Foley & Lardner](#)

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[Pharmacy Care](#)

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[Telehealth](#)

<https://news.bloomberglaw.com/health-law-and-business/telehealth-industry-pushes-dea-on-red-flags-for-prescriptions>

# FEDERAL

## FDA

- Can require REMS when potential risks of a drug outweigh the benefits
- Seeking prescribers' help in curtailing opioid epidemic by:
  - › Ensuring adequate training
  - › Knowing the content of the most current opioid drug labels
  - › Educating patients



# STATE

## LAWS

- Physical exam
- Tamper-resistant prescription pads
- Etc.

# STATE

## LICENSING BOARDS

- Prescribing for pain
- Overprescribing
  - › Prescription Drug Strike Force (CA)

# RISKS OF PRESCRIBING CONTROLLED SUBSTANCES

- To patients
- To third parties
- To prescribing physicians

# RISKS TO PATIENTS

- Side effects
  - › Including withdrawal
- Misuse
  - › OD
  - › Death
- Addiction
- Diversion

# RISKS TO THIRD PARTIES

- Diversion
- Third party injury

# RISKS TO PRESCRIBING PSYCHIATRISTS

- Civil litigation / medical malpractice
  - › Underprescribing for pain
  - › Overprescribing for pain
  - › Diversion, abuse, overdose
  - › Failure to recognize addiction
  - › Other
    - Patient's defense
    - Third party actions

# 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

# Importance of Discussing Potential Risks of Pain Medication on Vehicle Operation

By Brittan Durham, M.D.  
Health Quality Investigation Unit, Tustin Office

The Medical Board of California (Board) remains vigilant in its mission to protect the public and works with many government entities to identify adverse events, and preventable morbidity and mortality. The Board has partnered with the U.S. Drug Enforcement Administration (DEA) in investigating deaths associated with controlled substances.

The National Transportation Safety Board (NTSB), the federal agency charged with investigating civil aviation accidents in the United States as well as significant accidents on railroads, highways and waterways, is now voicing concerns regarding the use of controlled substances and the potential for impairment in driving, aviation, watercraft operations and accidents associated with working with heavy machinery.



The NTSB has recommended that state medical boards develop guidelines for prescribing controlled substances which include recommendations for health care providers to discuss with patients the effects their medical condition and medication use may have on their ability to safely operate motor vehicles, aircraft, boats, and any ancillary machinery.

The Board adopted the [Guidelines for Prescribing Controlled Substances for Pain \(Guidelines\)](#) with the intent

of helping physicians improve patient care outcomes and prevent morbidity and mortality associated with the use and misuse of controlled substances. The *Guidelines* include an informed consent and treatment agreement for those patients who are taking controlled substances on a medium- and long-term basis. The patient consent and a pain management agreement can be combined into one document for convenience.

When considering long-term use of opioids, physicians should discuss the risks and benefits of the treatment plan with the patient and document this process in the medical records. The risks of medication should be considered in the context of the patient's potential impairment with respect to activities such as driving, flying and working with machinery.

Risks as defined by the *Guidelines* include:

- Potential side effects (both short- and long-term) of the medication, such as nausea, opioid-induced constipation and cognitive impairment.
- The likelihood that some medications will cause tolerance and physical dependence to develop.
- The risk of drug interactions and over-sedation.
- The risk of respiratory depression.
- The risk of impaired motor skills (affecting driving and other tasks).
- The risk of opioid misuse, dependence, addiction and overdose.
- The limited evidence as to the benefit of long-term opioid therapy.

The treatment agreement should outline joint prescriber and patient responsibilities so there is a documented understanding that the patient agrees to use medications safely while performing tasks that might be compromised by impaired motor skills and cognitive function. It should highlight the importance of documented routine discussions regarding a patient's medical condition and the drugs he or she takes with respect to his or her ability to safely operate any transportation vehicle with the goal of preventing accidents and saving lives.



### **How should I take PROZAC?**

- Take PROZAC exactly as prescribed. Your healthcare provider may need to change the dose of PROZAC until it is the right dose for you.
- PROZAC may be taken with or without food.
- If you miss a dose of PROZAC, take the missed dose as soon as you remember. If it is almost time for the next dose, skip the missed dose and take your next dose at the regular time. Do not take two doses of PROZAC at the same time.
- If you take too much PROZAC, call your healthcare provider or poison control center right away, or get emergency treatment.

### **What should I avoid while taking PROZAC?**

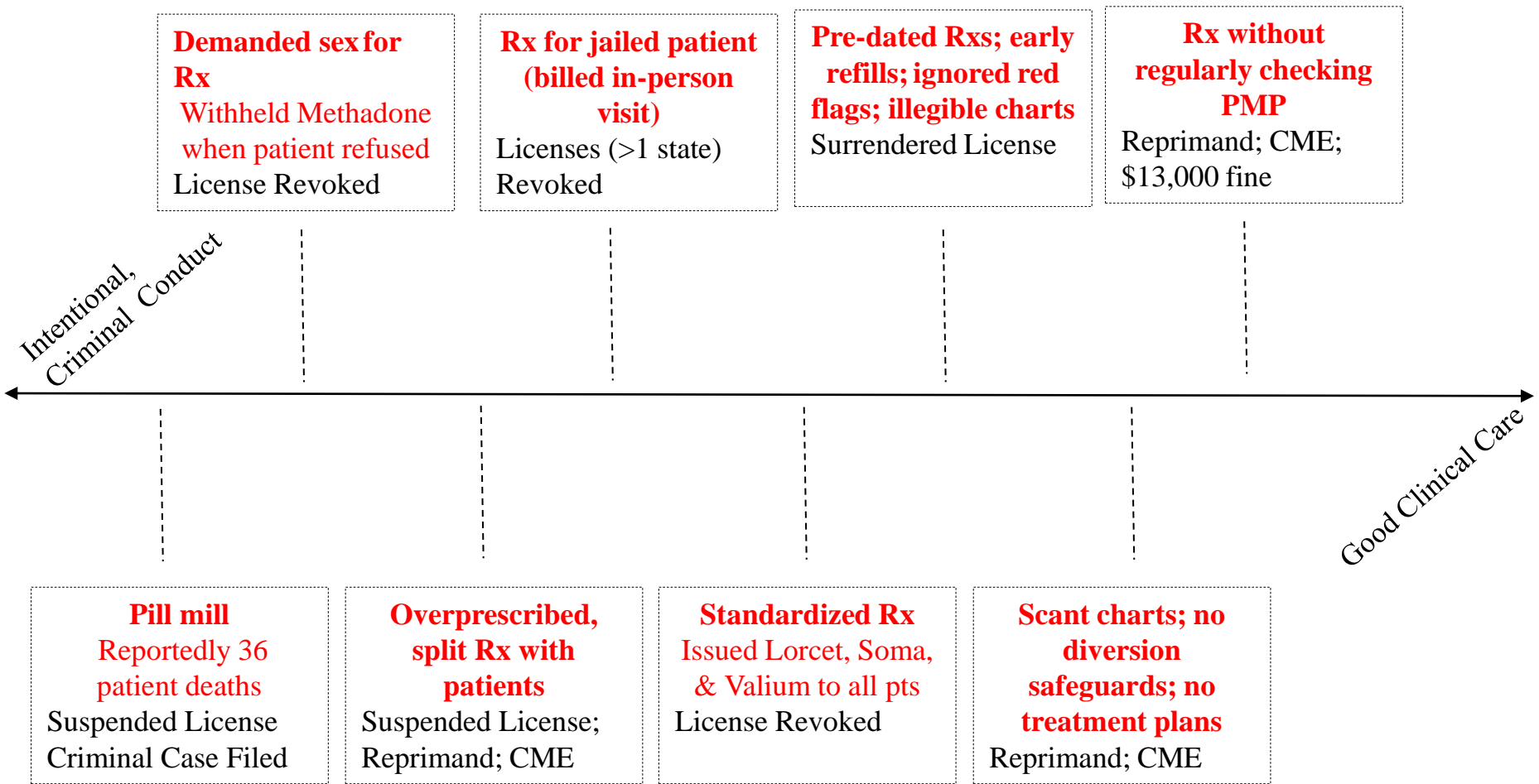
PROZAC can cause sleepiness or may affect your ability to make decisions, think clearly, or react quickly. You should not drive, operate heavy machinery, or do other dangerous activities until you know how PROZAC affects you. Do not drink alcohol while using PROZAC.

### **What are the possible side effects of PROZAC?**

PROZAC may cause serious side effects, including:

# RISKS TO PRESCRIBING PSYCHIATRISTS

- Licensing board action
- DEA action
- Criminal action



How to minimize professional liability risk



Utilize three risk management strategies to provide good clinical care



Strategy #1:

**COLLECTING  
INFORMATION**

Strategy #2:

**COMMUNICATING**

Strategy #3:

**CAREFULLY  
DOCUMENTING**

|

# COLLECT INFORMATION

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

# COLLECT INFORMATION – ABOUT THE PATIENT

- History
- PMP

# COLLECT INFORMATION – ABOUT THE MEDICATIONS

- REMS: Strategy to manage known or potential serious risks associated with a drug product and is required by the FDA to ensure the benefits of a drug outweigh its risks

# REMS ELEMENTS

- **MUST INCLUDE:**
  - › Timetable for assessments of strategy
- **MAY INCLUDE:**
  - › Medication guide; patient package insert
  - › Communication plan
  - › Elements to assure safe use (ETASU)

21 U.S.C.A. § 355-1(c)-(f) (West 2012).



# MEDICATION GUIDES

- Information needed to prevent serious adverse effects
- Support informed decision-making by patient
- Patient adherence to directions is essential to effectiveness
- E-mail alerts when updated

[www.fda.gov/Drugs/DrugSafety/ucm085729.htm](http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm)

# COMMUNICATION PLAN

- Letters to providers
- Disseminating REMS information to providers
  - › Encourage implementation of REMS
  - › Explain safety protocols, i.e., medical monitoring by periodic lab tests
- Using professional societies to educate providers on serious risks and protocols to assure safe use

21 U.S.C.A. § 355-1(e)(3) (West 2012).

# ELEMENTS TO ASSURE SAFE USE (ETASU)

- Provide safe access
- Minimize burden
- Assure safe use
  - › Prescriber training or certification
  - › Dispenser certification
  - › Dispensing restricted to hospitals or infusion centers
  - › Evidence of safe-use conditions, i.e., lab test results
  - › Specified patient monitoring
  - › Patient registry

21 U.S.C.A. § 355-1(f) (West 2012).

# ELEMENTS TO ASSURE SAFE USE (ETASU)

- Implementation system
  - › Monitor implementation by providers, etc.
  - › Work to improve implementation
- Evaluation
- Additional mechanisms to assure safe access
  - › Unapproved therapies
- Waiver in public health emergencies
- Limitation
  - › Shall not be used to block or delay approval of other drugs

21 U.S.C.A. § 355-1(f) (West 2012).

# COLLECT INFORMATION – ABOUT THE MEDICATIONS

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

## Medication Guides

[f Share](#)
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[Email](#)
[Print](#)

### Sign up for Medication Guide Alerts

Medication Guides (MGs) are a type of labeling for patients and caregivers that are required by the FDA when:

- The MG could help prevent serious side effects,
- The medicine has serious side effects (relative to benefits) in which patients should be made aware of, or
- Following directions for the use of the medicine is important for the medicine's effectiveness.

This database contains MGs for FDA-approved human prescription drugs and therapeutic biological products. Although this database does not include MGs for vaccines, allergenic products, blood products, plasma derivatives, and cellular and gene therapy products, such MGs can be found on [FDALabel](#) or [DailyMed](#). For more information about MGs see "[What are Medication Guides](#)" on the Patient Labeling Resources webpage.

To find a MG, start typing the name of the drug or the active ingredient(s) in the drug in the "Search" box. Click on the drug name to view the MG in PDF format.

Click on drug name to view Medication Guide in PDF format.

Show 25 rows

CSV

Excel

Print

Search:

Drug Name	Active Ingredient	Form;Route	Appl. No.	Company	Date
<a href="#">Abacavir and Lamivudine</a>	Abacavir Sulfate;Lamivudine	TABLET;ORAL	204311	MYLAN LABORATORIES LIMITED	12/22/2023
<a href="#">Ablify</a>	Aripiprazole	TABLET;ORAL	021436	OTSUKA	11/30/2022
<a href="#">Ablify</a>	Aripiprazole	SOLUTION;ORAL	021713	OTSUKA	02/05/2020
<a href="#">Ablify</a>	Aripiprazole	TABLET, ORALLY DISINTEGRATING;ORAL	021729	OTSUKA	02/05/2020
<a href="#">Ablify</a>	Aripiprazole	INJECTABLE;INTRAMUSCULAR	021866	OTSUKA	02/05/2020
<a href="#">Ablify Maintena Kit</a>	Aripiprazole	FOR SUSPENSION, EXTENDED RELEASE;INTRAMUSCULAR	202971	OTSUKA PHARM CO LTD	02/05/2020
<a href="#">Ablify Mycite Kit</a>	Aripiprazole	TABLET;ORAL	207202	OTSUKA	11/30/2022
<a href="#">Abrilada</a>	Adalimumab-Afzb	INJECTABLE;INJECTION	761118	PFIZER INC	10/04/2023
<a href="#">Absorica</a>	Isotretinoin	CAPSULE;ORAL	021951	SUN PHARM INDS INC	10/08/2021
<a href="#">Abstral</a>	Fentanyl Citrate	TABLET;SUBLINGUAL	022510	SENTYNL THERAPS INC	10/07/2019
<a href="#">Accutane</a>	Isotretinoin	CAPSULE;ORAL	018662	HOFFMANN LA ROCHE	10/22/2010
<a href="#">Aciphex</a>	Rabeprazole Sodium	TABLET, DELAYED RELEASE;ORAL	020973	WOODWARD	07/18/2023
<a href="#">Aciphex Sprinkle</a>	Rabeprazole Sodium	CAPSULE, DELAYED RELEASE;ORAL	204736	AYTU	11/27/2020
<a href="#">Actemra</a>	Tocilizumab	INJECTABLE; INJECTION	125276	GENENTECH	02/28/2022
<a href="#">Actemra</a>	Tocilizumab	INJECTABLE;INTRAVENOUS,	125472	GENENTECH	02/28/2022

[https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=medguide\\_page&utm\\_campaign=SBIA%3A%20FDA%20Launches%20New%20Medication%20Guide%20Database&utm\\_medium=email&utm\\_source=Eloqua](https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=medguide_page&utm_campaign=SBIA%3A%20FDA%20Launches%20New%20Medication%20Guide%20Database&utm_medium=email&utm_source=Eloqua)

# NEW SAFETY INFORMATION

## In response to new safety information, review the appropriateness of your prescriptions

- Communicate new information to patient – and document
- If medication is changed -
  - › Document your decision-making process
  - › Obtain informed consent
  - › Document informed consent discussions
- If not clinically appropriate to change -
  - › Document your decision-making process
  - › Obtain updated informed consent
  - › Document updated informed consent
  - › Consider modifying patient monitoring
  - › Do not hesitate to seek consultation

# 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

## COMMON CHARACTERISTICS OF THE DRUG ABUSER

- From the DEA:
  - › Unusual behavior in waiting room
  - › Assertive personality, often demanding immediate action
  - › Unusual appearance
  - › Unusual knowledge of controlled substances and/or textbook symptoms
  - › Evasive or vague answers to questions regarding medical history

# COLLECT INFORMATION – ABOUT ABUSE

## *(CONTINUED)*

- › Reluctant or unwilling to provide reference information
- › No regular doctor; no health insurance
- › Will request a specific controlled drug and is reluctant to try a different drug
- › No interest in diagnosis; fails to keep appointments for further diagnostic tests or refuses to see another practitioner for consultation
- › Exaggerates medical problems and/or simulates symptoms
- › Cutaneous signs of drug abuse

[http://www.deadiversion.usdoj.gov/pubs/brochures/pdfs/recognizing\\_drug\\_abuser\\_trifold.pdf](http://www.deadiversion.usdoj.gov/pubs/brochures/pdfs/recognizing_drug_abuser_trifold.pdf)

# COLLECT INFORMATION – ABOUT ABUSE

## COMMON CHARACTERISTICS OF THE DRUG ABUSER

- From the CA Department of Justice:
  - › Hesitates or is unclear about personal information
  - › Requests specific controlled substances
  - › Repeatedly runs out of medication early
  - › Rapid requests for increase in controlled substances

# COLLECT INFORMATION – ABOUT ABUSE

## COMMON CHARACTERISTICS OF THE DRUG ABUSER

- From the CA Department of Justice (Continued):
  - › After-hour, holiday or weekend requests for controlled substances
  - › Unscheduled refill requests
  - › Unwilling to try nonopioid treatment
  - › Ongoing use after medical problem has resolved
  - › Doctor-shopping
  - › Moving from one PCP to another frequently
  - › Evidence of withdrawal symptoms

# COLLECT INFORMATION – ABOUT ABUSE

## MODUS OPERANDI / SCAMS USED

- From the DEA:
  - › Must be seen right away
  - › Wants an appointment toward end of office hours
  - › Calls or comes in after regular business hours
  - › Traveling through town, visiting friends or relatives
  - › Feigning physical problems

# COLLECT INFORMATION – ABOUT ABUSE

## MODUS OPERANDI / SCAMS USED

- From the DEA (Continued):
  - › Feigning psychological problems
  - › States that specific non-narcotics do not work or he is allergic to them
  - › States prescription has been lost or stolen
  - › Requests refills more than originally prescribed
  - › Pressures by eliciting sympathy or guilt
  - › Utilizes a child or elderly person when seeking stimulants or narcotics

[http://www.deadiversion.usdoj.gov/pubs/brochures/pdfs/recognizing\\_drug\\_abuser\\_trifold.pdf](http://www.deadiversion.usdoj.gov/pubs/brochures/pdfs/recognizing_drug_abuser_trifold.pdf)

# 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/bnnd/doc/PreventingPrescriptionFraud.doc>



# COMMUNICATE – ASSESSMENT AND MONITORING

- Conduct thorough patient examination, interview, and assessment
- Consider standardized assessment and documentation tool
  - › Especially for pain
    - Ex: PADT from Janssen

# 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
- Disclose possible driving impairment
- Golden Rule

## Medication Guides

[f Share](#)
[Tweet](#)
[in LinkedIn](#)
[Email](#)
[Print](#)

### Sign up for Medication Guide Alerts

Medication Guides (MGs) are a type of labeling for patients and caregivers that are required by the FDA when:

- The MG could help prevent serious side effects,
- The medicine has serious side effects (relative to benefits) in which patients should be made aware of, or
- Following directions for the use of the medicine is important for the medicine's effectiveness.

This database contains MGs for FDA-approved human prescription drugs and therapeutic biological products. Although this database does not include MGs for vaccines, allergenic products, blood products, plasma derivatives, and cellular and gene therapy products, such MGs can be found on [FDALabel](#) or [DailyMed](#). For more information about MGs see "[What are Medication Guides](#)" on the Patient Labeling Resources webpage.

To find a MG, start typing the name of the drug or the active ingredient(s) in the drug in the "Search" box. Click on the drug name to view the MG in PDF format.

Click on drug name to view Medication Guide in PDF format.

Show 25 rows
CSV
Excel
Print

Search:

Drug Name	Active Ingredient	Form;Route	Appl. No.	Company	Date
<a href="#">Abacavir and Lamivudine</a>	Abacavir Sulfate;Lamivudine	TABLET;ORAL	204311	MYLAN LABORATORIES LIMITED	12/22/2023
<a href="#">Ablify</a>	Aripiprazole	TABLET;ORAL	021436	OTSUKA	11/30/2022
<a href="#">Ablify</a>	Aripiprazole	SOLUTION;ORAL	021713	OTSUKA	02/05/2020
<a href="#">Ablify</a>	Aripiprazole	TABLET, ORALLY DISINTEGRATING;ORAL	021729	OTSUKA	02/05/2020
<a href="#">Ablify</a>	Aripiprazole	INJECTABLE;INTRAMUSCULAR	021866	OTSUKA	02/05/2020
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<a href="#">Ablify Mycite Kit</a>	Aripiprazole	TABLET;ORAL	207202	OTSUKA	11/30/2022
<a href="#">Abrilada</a>	Adalimumab-Afzb	INJECTABLE;INJECTION	761118	PFIZER INC	10/04/2023
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<a href="#">Accutane</a>	Isotretinoin	CAPSULE;ORAL	018662	HOFFMANN LA ROCHE	10/22/2010
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<a href="#">Actemra</a>	Tocilizumab	INJECTABLE; INJECTION	125276	GENENTECH	02/28/2022
<a href="#">Actemra</a>	Tocilizumab	INJECTABLE;INTRAVENOUS,	125472	GENENTECH	02/28/2022

[https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=medguide\\_page&utm\\_campaign=SBIA%3A%20FDA%20Launches%20New%20Medication%20Guide%20Database&utm\\_medium=email&utm\\_source=Eloqua](https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=medguide_page&utm_campaign=SBIA%3A%20FDA%20Launches%20New%20Medication%20Guide%20Database&utm_medium=email&utm_source=Eloqua)

# 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

# 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
  - › Etc.

# COMMUNICATE – DISPOSAL OF UNUSED MEDICATIONS

The FDA's

**“Disposal of Unused Medicines: What You Should Know”**

<http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/ensuringsafeuseofmedicine/safedisposalofmedicines/ucm186187.htm>

# 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

# 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.

# Prescribing Controlled Substances

## PILL “PUSHER”/ PILL MILL

- No medical history
- Inadequate, or no physical examination
- No informed consent
- Lack of urine screens, or results ignored
- No documentation of prescriptions
- Very large quantities prescribed
- Large number of prescriptions
- PMP not checked, or results ignored
- Lack of monitoring
- No documentation
- No logical relationship between medications prescribed and treatment and alleged condition
- No precautions against abuse or misuse
- No communication with other providers
- Information from third parties (pharmacists, other providers, etc.) ignored
- Patients charged based on number of pills prescribed

## LEGITIMATE PATIENT CARE

- Medical history
- Physical examination
- Informed consent obtained, including discussion of applicable driving risks
- Random urine testing
- Prescription details documented
- Clinically appropriate quantities prescribed
- Reasonable number of prescriptions provided
- PMP checked and information incorporated into treatment
- Patient monitoring - drug screens and adequate time spent with patient
- Documentation of decision-making process
- Evidence to support medications for patient’s condition
- Treatment agreement including only one pharmacy requirement, prescription rules, termination for non-adherence, etc.
- Communication and coordination with other prescribers
- Information from third parties is considered and treatment is revised accordingly
- Appropriate billing for treatment provided



# PSYCHEDELICS

- Compounds creating non-ordinary states of consciousness
- Subgroups:
  - › Classical psychedelics
    - LSD
    - Psilocybin
    - Mescaline
    - DMT
  - › Empathogens
    - MDMA
  - › Dissociative anesthetics
    - Ketamine

# KETAMINE

## Routes of administration

- IV
- IN
  - › Spravato (REMS)
  - › Compounded version = unapproved drug
    - Check with your liability insurance company
- Oral

# KETAMINE-ASSISTED PSYCHOTHERAPY (KAP)



## ABOUT

*"Johns Hopkins is deeply committed to exploring innovative treatments for our patients. Our scientists have shown that psychedelics have real potential as medicine, and this new center will help us explore that potential."*

## KAP – RISK CONTINUUM

- LOWEST RISK if psychiatrist does both the ketamine administration and psychotherapy in person
- RELATIVELY LOW RISK if psychiatrist prescribes oral ketamine and psychiatrist's own licensed therapist trained in KAP does KAP
- HIGHER RISK if psychiatrist prescribes oral ketamine and does psychotherapy remotely

# KAP – RISK CONTINUUM

- VERY HIGH RISK if psychiatrist wants to prescribe ketamine and
  - › Unrelated therapists does remote KAP
- OR
- › Psychiatrist works for online ketamine business where no therapist is involved in the “experience”
  - Not really KAP, no matter what the business calls it





# PANDEMIC – REGULATORY WAIVERS

- Federal law temporarily waived:
  - › In-person visit prior to prescribing controlled substances
  - › DEA registration in patient's state (as well as in prescriber's state)
- State law temporarily waived:
  - › State licensure
  - › State in-person visit requirements re: controlled substances

# KETAMINE 'BUSINESSES' POPPED UP

- Direct to consumer
- Online businesses disclaim all liability –
  - › All on prescribers
- Query: “valid prescription” under CSA?

## FROM PEAK'S WEBSITE

“We believe that everyone has a right to  
choose their own modality of care.  
No one should tell you how to heal yourself.”

??

# PROBLEMS HAVE EMERGED

- With regulators
  - › DEA investigations
- In the courts
  - › Medical malpractice

# KETAMINE – RISK MANAGEMENT ADVICE

- Understand the risks
- Keep up with the research
- Only use ketamine as part of your patient care
- Understand the risks associated with working with online ketamine companies
- Be familiar with guidelines
- Contact your professional liability insurance company

# MEDICAL MARIJUANA



# APA Resource Document

## Resource Document on Opposition to Cannabis as Medicine

Approved by the Joint Reference Committee, October 2018

"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*.

Prepared by the Council on Addictions

### **Abstract**

The medical use of cannabis has received considerable attention as several states have voted to remove civil and criminal penalties for patients with qualifying conditions. Yet, on a national level, cannabis remains a schedule I substance under the Controlled Substances Act (CSA), the most restrictive schedule enforced by the Drug Enforcement Administration (DEA) (1). The Food and Drug Administration (FDA), responsible for approving treatments after appropriate and rigorous study, has not approved cannabis as a safe and effective drug for any indication (2). This juxtaposition of practice and policy has prompted many professional medical organizations to issue official positions on the topic. This statement reflects the position of the American Psychiatric Association (APA) on the use of cannabis for medical and psychiatric indications, taking into account the current evidence base and statements from other medical organizations. It does not cover the use of synthetic cannabis-derived medications such as Marinol and Syndros (dronabinol), Cesamet (nabilone) or Epidiolex (contains a purified drug substance



# APA RESOURCE DOC: CANNABIS FOR PTSD (2019)

- **Summary of studies:** “As of yet, there are no published high quality, randomized, controlled studies evaluating the effects of botanical cannabis or synthetic, pharmaceutical cannabinoids on PTSD outcomes.”
- **Risks:**
  - › Coping strategy vs. being clinically addressed
  - › Withdrawal symptoms
- **Summary:** “Given the lack of evidence for cannabis use in the treatment of PTSD and the risks associated with continued avoidance and worsening of symptoms, there needs to be more studies conducted prior to instituting changes in practice and policy regarding cannabis in patients with PTSD. The APA does not endorse cannabis for the treatment of PTSD”

# 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

# Medical Marijuana Recommendations

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, such as:

- 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

# PSYCHOPHARMACOLOGY - RESOURCES

- PRMS newsletters:
  - › Part 1
  - › Part 2

# AGENDA

- Introduction
- Technology
  - › Telepsychiatry
  - › EHRs
  - › Social media
- Psychopharmacology
- 10 things about....

# 10 THINGS – BILLING & COLLECTIONS

1. Discuss policies with patients and have patients agree in writing
2. Patient needs to agree to no-show fee prior to charging
3. Need credit card owner's signature on file
4. You cannot refuse to treat until paid
5. Do not allow balances to get too large

# 10 THINGS – BILLING AND COLLECTIONS

6. Follow rules prior to sending patient to collections
7. Sending patient to collections could result in lawsuit or board complaint
8. Need BAA from collections agency
9. Do not share clinical information with collections agency
10. Ensure compliance with health plan contracts



# BILLING & COLLECTIONS - RESOURCES

- PRMS articles:
  - › Practical Pointers for Using a Collection Agency
  - › To Collect Or Not to Collect?

# 10 THINGS – CONTRACTS

1. Need to be in writing
2. Once you sign a contract, it is generally enforceable
3. Low bar for seeking consult from your attorney
4. Do not rely on others re: need for licensure
5. Have vague or ambiguous language clarified\

## 10 THINGS – CONTRACTS

6. Watch for provisions requiring substandard care
7. BAA may be needed
8. Avoid indemnification provisions
9. Know the term of the agreement and how to end it
10. Watch for venue in case of disagreement

# CONTRACTS - RESOURCES

- PRMS contracts booklet
  - › Employment
  - › Office
  - › Record storage
  - › Technology

# 10 THINGS – DOCUMENTATION

1. 3 purposes – clinical care, billing, defense
2. No such thing as a perfect record
3. Explains your decisions
4. States and payers may have requirements
5. Defense counsel can work with adequate records

# 10 THINGS – DOCUMENTATION

6. Defense counsel cannot work with no records
7. Include what you considered but rejected and why
8. Document discreetly – patients can see
9. Document discreetly – third parties will see
10. Notes from psychotherapy ≠ psychotherapy notes under HIPAA

# DOCUMENTATION - RESOURCES

- PRMS articles
  - › Newsletter

# 10 THINGS – INFORMED CONSENT

1. Competent adults have the right to accept or reject treatment
2. Needed for medications
3. In litigation, no negligence is required
4. Is ongoing communication process
5. Is not a form



## 10 THINGS – INFORMED CONSENT

6. Need nature and purpose of proposed treatment, potential risks and benefits of proposed treatment and of alternative treatments, and risks of doing nothing
7. Communication must be understood by patient
8. Risks include those significant, even if not frequent, and those frequent, even if not significant
9. Include patient questions in documentation of consent discussions
10. Do not rely on consent obtained by prior treaters

# INFORMED CONSENT - RESOURCES

- PRMS article
  - › Informed Consent – More Than a Piece of Paper
- ICNS article
  - › [Consent to Treatment of Minors](#)

# 10 THINGS – NONADHERENT PATIENTS

1. Nonadherence may not be obvious
2. Often results in inadequate or incomplete treatment
3. May be evidenced by missed appointments, failure to get lab work, failing to take meds, engaging in inappropriate behaviors, etc.
4. Reasons for nonadherence need to be investigated
5. Health literacy may be an issue

# 10 THINGS – NONADHERENT PATIENTS

6. May be due to lack of patient insight into condition
7. May be due to medication side effects
8. Documentation is key
9. Patients have the right to disagree with treatment plan
10. You cannot continue to treat if patient does not agree with the treatment plan and does not allow you to meet the standard of care

# 10 THINGS – VIOLENT PATIENTS

1. Evaluation and ongoing care of potentially violent patients include the assessment of risk of harm to self and/or others.
2. Components of assessment – identify risk factors, assess overall risk, document, determine treatment
3. When treating patients with history of violent behavior, make efforts to obtain past treatment records.
4. Discuss limits of confidentiality at the outset.
5. Where appropriate, get family members involved so they understand their role in dealing with patient violence.

# 10 THINGS – VIOLENT PATIENTS

6. Thorough record keeping is essential – risk factors, protective factors, overall assessment, treatment, re-assess.
7. Know the standards and procedures for commitment.
8. Consider safety of yourself and staff.
9. Carefully consider what you can say in letter requested by patient.
10. If necessary, terminate appropriately – and document!

# VIOLENT PATIENTS - RESOURCES

- PRMS articles:
  - › Violent Patients
  - › Patient Violence against Clinicians

# 10 THINGS – SUICIDE

1. Psychiatrists are not required to predict and prevent all suicide attempts to avoid liability.
2. Obtain past treatment records, and if unable, document your efforts.
3. Utilize a formal suicide risk assessment tool.
4. Address safety of environment, including access to weapons.
5. Document which treatment options were chosen and why and which options were considered but rejected and why.



## 10 THINGS – SUICIDE

6. Reassess suicide risk when there is ideation/harm, modification to observation, discharge/transfer to another level of care, or other significant change.
7. Only enter split treatment if comfortable with the other provider.
8. Patient safety trumps confidentiality.
9. Do not rely solely on “no harm” contracts.
10. Know civil commitment procedures in your state.

# Suicide Assessment and Treatment Course 2023

National experts respond to our field's most pressing clinical challenge

The suicide rate has increased significantly over the past two decades, with nearly 50,000 people currently dying from suicide in America each year.

To respond to our field's most pressing clinical challenge, experts from across the country presented the most recent, cutting-edge advances in suicide-focused assessment and treatment, including the current efficacy of somatic and psychological interventions, the use of new clinical technologies, and considerations for special populations including groups disproportionately affected by suicide.

Presented by McLean Hospital and the Department of Psychiatry and Behavioral Sciences at the Stanford University School of Medicine.

This event took place on October 25, 2023.

Watch the sessions on demand below or view the [event agenda](#).

<https://www.mcleanhospital.org/ce-suicide-2023>

# SUICIDE - RESOURCES

- PRMS newsletters
  - › Part 1
  - › Part 2

# 10 THINGS – NURSE PRACTITIONERS

1. Psychiatrists are often named in malpractice cases against their NP supervisees – regardless of patient contact.
2. Two primary sources of negligence: vicarious liability and negligent supervision.
3. Before agreeing to supervision, meet the NP to determine your level of comfort.
4. Know your state's requirements regarding scope of practice and supervision.
5. States set forth minimum requirements necessary – psychiatrist may require closer supervision.

# 10 THINGS – NURSE PRACTITIONERS

6. Utilize a supervision/collaboration agreement.
7. Check your state's nursing board website for sample supervision agreements and other resources.
8. The psychiatrist should have the time available and temperament necessary for supervision.
9. Before hiring an NP, verify their credentials.
10. Patients should be informed they will be seeing an NP and allowed to see a psychiatrist if preferred.

# NURSE PRACTITIONERS - RESOURCES

- PRMS article
  - › Supervision of Nurse Practitioners

# 10 THINGS – GEROPSYCHIATRIC PATIENTS

1. Capacity to give informed consent to treatment may be impaired.
2. May lack the capacity to make certain decisions but not others.
3. May need a surrogate decision-maker to consent to treatment.
4. More likely to have co-occurring somatic conditions.
5. Increased risk of over/under-medicating patients.

# 10 THINGS – GEROPSYCHIATRIC PATIENTS

6. To the extent allowed by the patient, it may be beneficial to involve family members.
7. Older adults have higher suicide rates than other age groups.
8. Suicide attempts are usually well-planned, often involving firearms.
9. Psychiatrists may be required to report abuse of elderly adults.
10. Patients may be reluctant to report abuse to treaters.



# GEROPSYCHIATRIC PATIENTS - RESOURCES

- PRMS article
  - › Practical Pointers for the Treatment of Geropsychiatric Patients
- ICNS article
  - › [Managing Your Aging Patient Population](#)

# 10 THINGS – TERMINATION

1. Once treatment has been established, care must be provided until the relationship has been properly terminated.
2. Treatment may be terminated by the patient or by the psychiatrist provided appropriate notice has been given to the patient.
3. There are many valid reasons to terminate treatment – keep clinical if possible; no discrimination.
4. The termination process should begin with a discussion if possible.
5. Length of notice = usually 30 days; may depend on patient's condition and available resources.

## 10 THINGS – TERMINATION

6. Discuss explicit treatment instructions and the risks of not obtaining recommended treatment.
7. Must provide suggestions for continued care, not necessarily specific names of psychiatrists.
8. A written termination communication should be sent memorializing your discussion.
9. Your record should reflect your decision-making process and communications regarding termination.
10. You remain responsible for meeting clinical needs during the notice period.

# LSBME ADVISORY OPINION

## **Advisory opinion: Termination of the Patient-Physician Relationship**

The Board is commonly asked for guidance on how to appropriately and ethically terminate a Patient-Physician relationship and avoid any claims of patient abandonment. In preparing this guidance document, the Board first looked to the AMA Code of Medical Ethics, which states:

*“Physicians have an obligation to support continuity of care for their patients. While physicians have the option of withdrawing from a case, they cannot do so without giving notice to the patient, the relatives, or responsible friends sufficiently long in advance of withdrawal to permit another medical attendant to be secured.”*

In order for a physician to maintain his or her ethical obligations to patients, we make the following recommendations for physicians intending to terminate the patient/physician relationship.

1. Notify the patient in writing of intent to dismiss and give a specific date, generally 30 days
2. Provide a brief explanation of why you are terminating the doctor/patient relationship
3. Document the notification, and reason for the termination in the patient's medical record
4. Assist patient in locating another provider by providing referral resources
5. Transfer all medical records to new provider immediately upon receipt of valid patient authorization form
6. Assure the patient has adequate refills of maintenance medications to assure continuity of care

# MSBML POLICY 3.18

Regardless of the situation, to avoid a claim of "patient abandonment", a physician must follow appropriate steps to terminate the physician-patient relationship. A physician may not discontinue treatment of a patient as long as further treatment is medically indicated, without giving the patient reasonable notice and sufficient opportunity to make other arrangements for care. A physician who does not terminate the relationship properly may be charged with unprofessional conduct.

Appropriate steps to terminate the physician-patient relationship include:

1. Giving the patient or patient's representative written notice, which may be by certified mail, return receipt requested, or other reasonable proof. A copy of the letter should be included in the medical record.
2. Providing the patient with a brief and valid reason for terminating the relationship.
3. Agreeing to continue to provide care for a reasonable period of time (at least 30 days) in order to allow the patient to obtain care from another physician.
4. Providing recommendations to help the patient locate another physician of like specialty.
5. Offer to transfer records to the new physician upon signed authorization and include an authorization form with the letter.
6. A physician assistant or nurse practitioner may not independently terminate the physician-patient relationship.

**Adopted July 10, 2008.**

# TERMINATION - RESOURCES

- PRMS article
  - › Termination of the Physician-Patient Relationship (includes model termination letters)
- ICNS article
  - › [Myths & Misconceptions: Terminating Treatment](#)

# 10 THINGS – STARTING A PRIVATE PRACTICE

1. Consider developing professional relationships with an experienced colleague/mentor, an attorney, and an accountant.
2. Ensure adequate professional liability coverage for all services provided, roles undertaken, and staff hired.
3. Review your licensing board website and understand state laws/regulations related to the practice of medicine (prescribing requirements, documentation standards, civil commitment procedures, etc.)
4. Join and participate in professional organizations.
5. If sharing office space, avoid the appearance of supervision or control.

# 10 THINGS – STARTING A PRIVATE PRACTICE

6. Determine whether you're a HIPAA CE and comply accordingly.
7. Establish and train staff on internal practice procedures.
8. Ensure any staff member who will access patient information signs a confidentiality agreement.
9. Draft and provide practice policies for patients.
10. It's never too early to start contingency planning.



# STARTING A PRIVATE PRACTICE - RESOURCES

- PRMS articles
  - › Starting a Private Practice
  - › Office Sharing and Liability Risks
- PRMS tool
  - › Contingency planning
- ICNS article
  - › [Emergency Planning](#)

## **INSTRUCTIONS TO RECEIVE CONTINUING MEDICAL EDUCATION CREDIT**

**At the conclusion of the webinar:**

**1. Go to**

**<https://prms-oevmw.formstack.com/forms/lpmamps2024>**

**2. Complete the entire survey.**

**CME certificates will be emailed to you within 3 weeks of survey completion.**

**If you have any CME questions or concerns, contact:**

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PRMS  
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