PRACTICING OUTSIDE OF YOUR COMFORT ZONE: MEETING THE GROWING NEED FOR PSYCHIATRIC CARE

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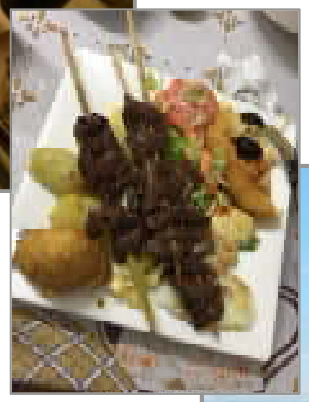
Arlington, VA
June 22, 2019

DAVID CASH, JD, LLM



DISCLOSURES

Ms. Vanderpool, Mr. Cash, and Mr. Pope have no relevant financial relationships with commercial interests.

DISCLAIMERS

- PRMS funded the initial distribution of the SAFE-T cards to residency programs years ago.
- Nothing we say today is legal advice.

OBJECTIVES

- Compare and contrast liability when treating adult patients versus minor patients
- Reconcile a parent's demand for information with a minor patient's right to confidentiality
- Explain the requirements of 42 CFR Part 2 for the confidentiality of substance use disorder treatment records
- Recognize when to incorporate a capacity determination into your informed consent communications with geriatric patients
- Identify various risks and management strategies to minimize professional liability exposure when recommending medical marijuana
- Describe three areas of research performed by psychiatric trainees

AGENDA

- Practicing outside of your comfort zone
  - Geropsychiatry
  - Child & adolescent psychiatry
  - Addiction psychiatry
- Medical marijuana
- Poster presentations
- Questions and paperwork

GERIATRIC PSYCHIATRY

WHAT WE'LL COVER

- Capacity
- Prescribing
- Abuse and neglect
- Communication
- Suicide risk assessments
- Driving issues

CAPACITY

Recognize that an elderly patient's capacity to give informed consent to treatment may be impaired

CAPACITY

Capacity = ability to:

- Communicate a choice
- Understand relevant information
- Appreciate medical consequences
- Reason about treatment choices

(Assessment of Patients' Competence to Consent to Treatment. N Engl J Med 2007; 357:1834-1840)

CAPACITY

- Fluid
- Different requirements for different decisions

CAPACITY

Two ways to assess:

- Formal assessment tool
- Clinical interview – determining patient's ability to:
  - Understand proposed treatment and treatment alternatives
  - Apply this information to his own medical situation
  - Reason with the information
  - Communicate and express a choice clearly

(Appelbaum, Clinical issues in the assessment of competency. Am J Psychiatry. 1981;138(11):1462–1467)

AMERICAN PSYCHIATRIC ASSOCIATION

> Psychiatrists > Practice > Professional Interests >

Geriatric Psychiatry

Position Statements

Role of Psychiatrists in Assessing Driving Ability (2016)

Role of Psychiatrists in Reducing Physical Health Disparities in Patients with Mental Illness (2015)

Ensuring Access to, and Appropriate Utilization of, Psychiatric Services for the Elderly (2015)

Elder Abuse, Neglect, and Exploitation (2018)

HIV Infection and People Over 50 (2008)

Resource Documents

Integrated Care of Older Adults with Mental Disorders (2009)

Use of Antipsychotic Medications to Treat Behavioral Disturbances in Persons with Dementia (2014)

Practice Guidelines from APA Publishing

Use of Antipsychotics to Treat Agitation or Psychosis in Patients with Dementia

Alzheimer's Disease and Other Dementias

Find a complete selection of books and publications related to Geriatric Psychiatry from APA Publishing.

www.psychiatry.org/psychiatrists/practice/professional-interests/geriatric

CAPACITY

Surrogate decision makers:

- Guardian
- Healthcare Power of Attorney

* Get copy of the document *

CAPACITY

PAD – Psychiatric Advance Directive

- Advance directive planned for mental health decisions

Newsroom

News Releases

Psychiatric News

Message from President

APA Blogs

Back to Blog List

Dec 14,2016 · APA Staff · Comments (0)

Psychiatric Advance Directives: Planning for Mental Health Care

Many people are familiar with advance directives that allow people to provide instructions for their care in the event that are unable to make decisions or communicate preferences. These typically apply in end-of-life care situations.

A psychiatric advance directive (or PAD) is similar in many respects, but is specific to mental health care. A psychiatric

Blog Categories

Addiction (90)

ADHD (59)

Alzheimer's (43)

Anxiety (114)

Autism (54)

Bipolar Disorders (88)

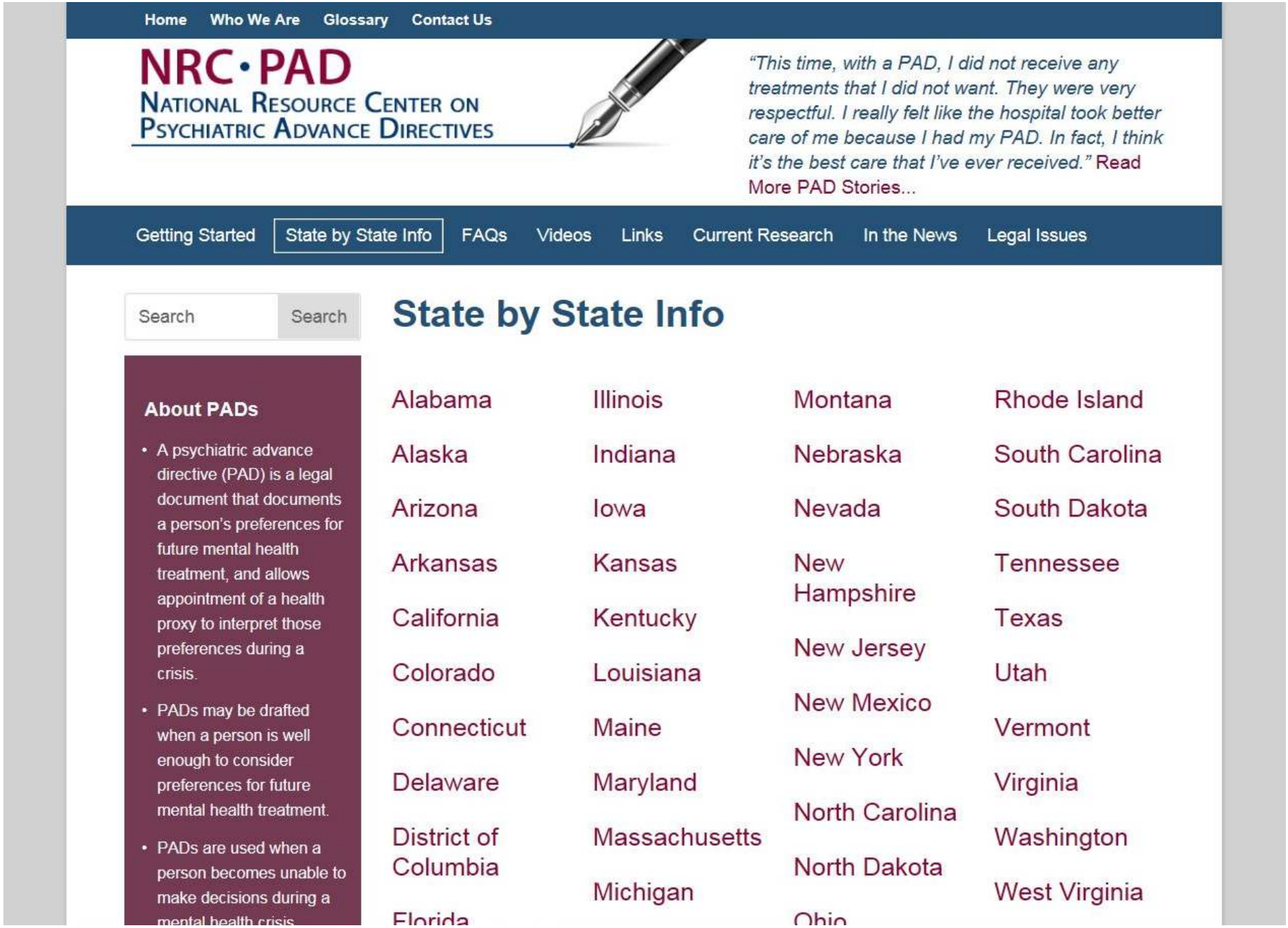
CEO Blog (35)

Conduct Disorders (4)

Depression (129)

Dissociative Disorders (46)

www.psychiatry.org/news-room/apa-blogs/apa-blog/2016/12/psychiatric-advance-directives-planning-for-mental-health-care



www.nrc-pad.org/states/

PRESCRIBING

Recognize that prescribing medication requires special attention to ensure the safety of elderly patients

Psychiatric Times

Identifying and Reducing Professional Liability When Treating Older Adults Actions You Can Take to Decrease Risks While Increasing Patient Safety

Jacqueline M. Melonas, RN, MS, JD
Charles D. Cash, JD

Psychiatric Times, January 2, 2009

PRESCRIBING

Before prescribing:

- Be current
- Be aware of all meds your patient currently takes
- Check the PMP
- Communicate with other prescribers
- Be aware of the ↑ risk of falls
- Discuss risks, including
  - Falls
  - Driving impairment

PRESCRIBING

After prescribing:

- Provide written instructions
- Simplify dosing
- Have patient use only one pharmacy
- Risks of under- and over-medicating
- Document clinical basis for your prescribing decisions

ABUSE AND NEGLECT

Understand your state's law regarding reporting of elder abuse or neglect

ABUSE AND NEGLECT

Concerns:

- Physical abuse
- Sexual abuse
- Psychological or verbal abuse
- Financial exploitation
- Neglect

ABUSE AND NEGLECT

Signs of caregiver mistreatment:

- Anger / frustration toward patient
- Lack of knowledge / indifference re: patient's condition
- History of doctor-hopping by caregiver
- Implausible explanations of patient's condition
- Attempts to keep patient from speaking to you

ABUSE AND NEGLECT

Signs of caregiver mistreatment:

- Failing to visit patient in hospital
- Inappropriate display of affection toward patient
- Apparent financial dependence on patient
- Excessive concern of treatment costs
- Caregiver has substance abuse / mental health issues

(Read, 2016)

STETSON LAW

CALIFORNIA

Statutes & Case Law	Who Has to Report? (Mandated Reporters)	When to Report	How to Report (& Other Resources)
Cal. Welf. & Inst. Code § 15630 *People v. Davis*, 25 Cal. Rptr. 3d 92 (Cal. App. 4th Dist. 2005). (Mandatory reporting requirement of Elder Abuse and Dependent Adult Civil Protection Act is governed by objective standard, and thus Act does not permit mandated reporter to apply his or her subjective expertise to determine if abuse occurred; if the circumstances give rise to an objective basis for suspecting that abuse occurred, reporting is mandatory, and the duty to investigate and the authority to determine whether abuse actually did occur are vested in outside agencies.)	Any person who has assumed full or intermittent responsibility for the care or custody of an elder or dependent adult whether or not he or she receives compensation, including administrators, supervisors, and any licensed staff of a public or private facility that provides care or services for elder or dependent adults, or any elder or dependent adult care custodian, health practitioner, clergy member, or employee of a county adult protective services agency or a local law enforcement agency is a mandated reporter.	Any mandated reporter who, in his or her professional capacity, or within the scope of his or her employment, has observed or has knowledge of an incident that reasonably appears to be physical abuse, as defined in Section 15610.63, abandonment, abduction, isolation, financial abuse, or neglect, or is told by an elder or dependent adult that he or she has experienced behavior, including an act or omission, constituting physical abuse, as defined in Section 15610.63, abandonment, abduction, isolation, financial abuse, or neglect, or reasonably suspects that abuse.	Reports shall be made by telephone or through a confidential Internet reporting tool, as authorized by Section 15658, immediately or as soon as practicably possible. If reported by telephone, a written report shall be sent, or an internet report shall be made through the confidential Internet reporting tool, within two working days, as follows: If the abuse occurred in a long-term care facility, except a state mental health hospital or a state developmental center, shall be made to the local ombudsperson or the local law enforcement agency. Must be within 2 hours if serious bodily injury, else within 24 hours. If the abuse occurred in a state mental hospital or a state developmental center, shall be made to designated. If the abuse has occurred any other place, the report shall be made to the adult protective services agency or the local law enforcement agency investigators of the State Department of Mental Health or the State Department of Developmental Services, or to the local law enforcement agency. From the CDSS Web site, follow the "Report Abuse" link to find COUNTY APS information. www.dss.cahwnet.gov/cdssweb.

The Center for Excellence in ELDER LAW ACCESS AND JUSTICE FOR ALL

ELDER CONSUMER PROTECTION PROGRAM

www.justice.gov/elderjustice/elder-justice-statutes-0
www.stetson.edu/law/academics/elder/home/media/Mandatory-reporting-Statutes-for-elder-abuse-2016.pdf

COMMUNICATION

Communication with family members and other caretakers may be needed

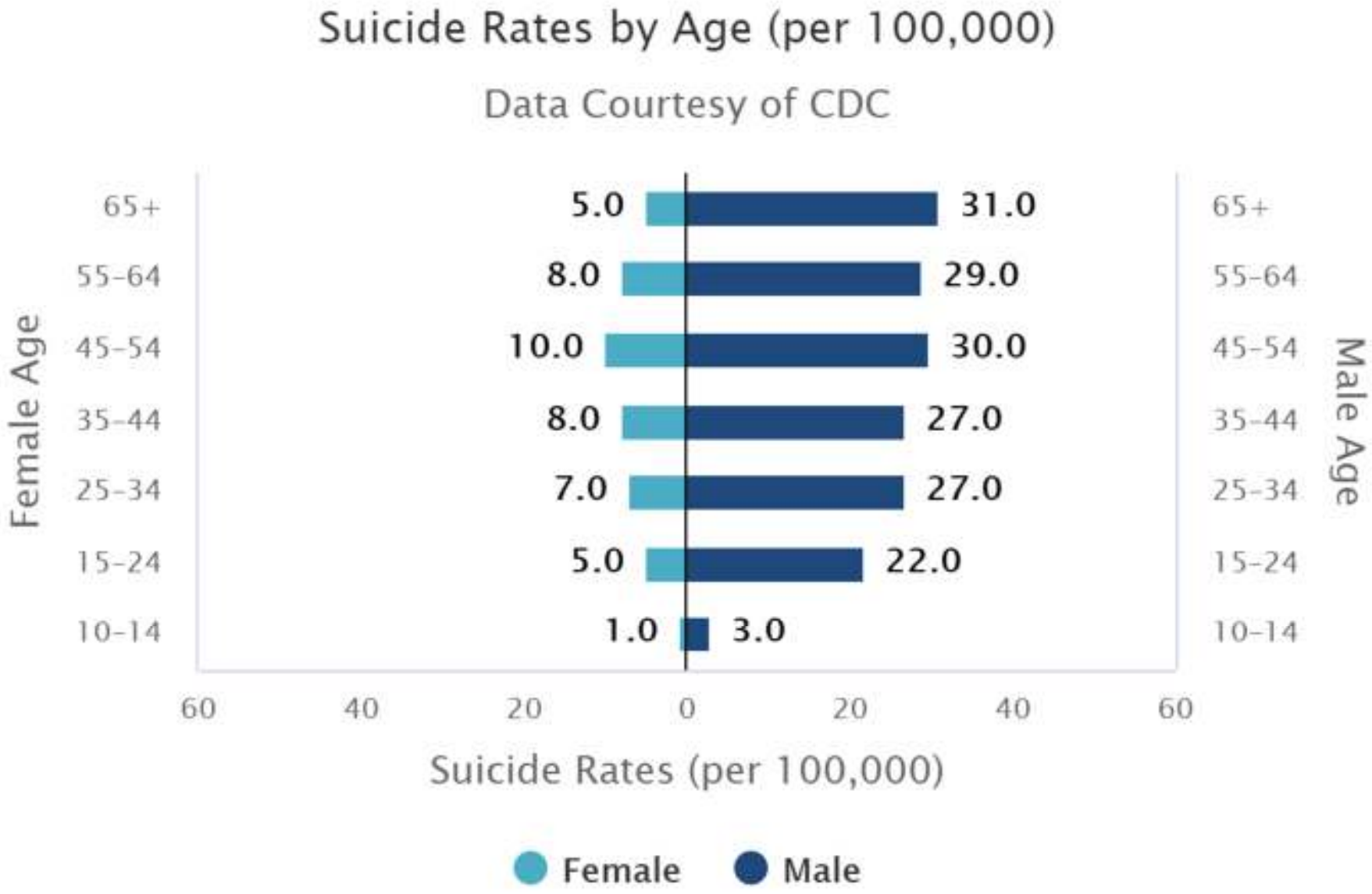
COMMUNICATION

Risk management advice:

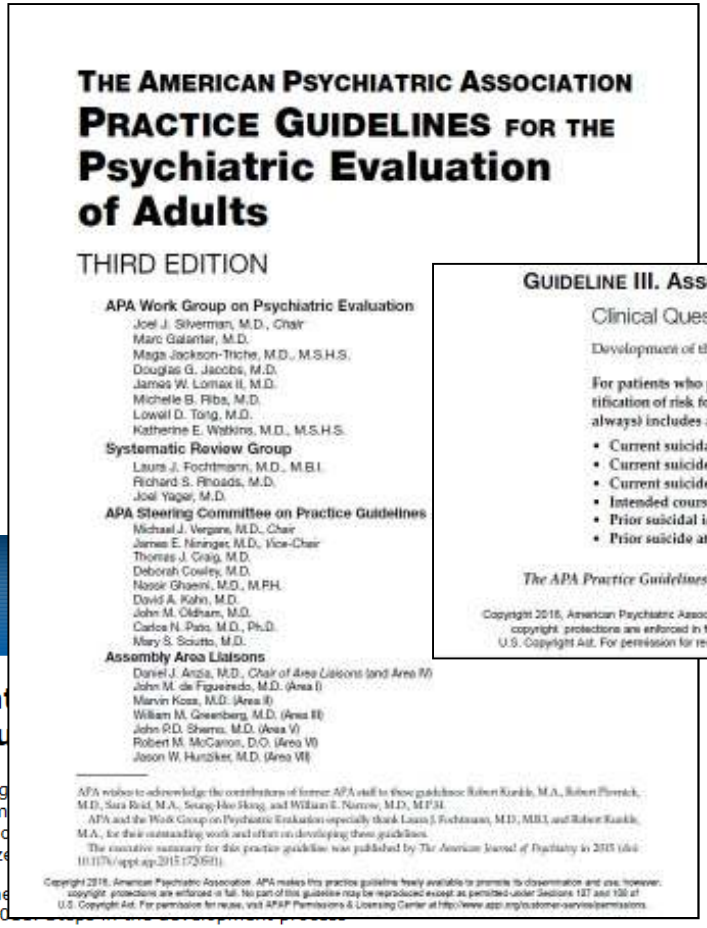
- Provide written information
- Ask patient about family involvement
- Ensure caregivers understand
  - Medication
  - Potential side effects
- Direct comments to both caregiver and patient
- Do not ignore calls from concerned family
  - Listening ≠ breach of confidentiality

SUICIDE RISK ASSESSMENTS

Understand that older patients have high suicide rates that other age groups



www.nimh.nih.gov/health/statistics/suicide.shtml



THE AMERICAN PSYCHIATRIC ASSOCIATION

PRACTICE GUIDELINES FOR THE Psychiatric Evaluation of Adults

THIRD EDITION

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GUIDELINE III. Assessment of Suicide Risk

Clinical Questions

Development of this guideline was premised on the following clinical questions:

For patients who present with a psychiatric symptom, sign, or syndrome in any setting, is identification of risk for suicide improved when the initial psychiatric evaluation typically (i.e., almost always) includes assessment of the following?

- **Current suicidal ideas, including active or passive thoughts of suicide or death**
- **Current suicide plans**
- **Current suicide intent**
- **Intended course of action if current symptoms worsen**
- **Prior suicidal ideas or suicide plans**
- **Prior suicide attempts**

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American Psychiat
Practice Gu

American Psychiatric Association (APA) practice g
recommendations for the assessment and treatm
guidelines are intended to assist in clinical decisio
developed patient care strategies in a standardize

In 2011, APA adopted a new guideline developme
of the Institute of Medicine published in March 20
include establishing transparency, managing conflicts of interest, composing work groups, using systematic reviews of evidence, articulating and rating recommendations in guidelines, obtaining external review, and updating. For additional information regarding the new process and a list of the current membership of the APA Steering Committee on Practice Guidelines, please visit the **American Psychiatric Association.**

Recently Published

(APA, 2016)

SUICIDE RISK ASSESSMENTS

SAFE-T

- https://store.samhsa.gov/product/SAFE-T-Pocket-Card-Suicide-Assessment-Five-Step-Evaluation-and-Triage-for-Clinicians/sma09-4432

Columbia scale

- https://suicidepreventionlifeline.org/wp-content/uploads/2016/09/Suicide-Risk-Assessment-C-SSRS-Lifeline-Version-2014.pdf

APA Practice Guidelines

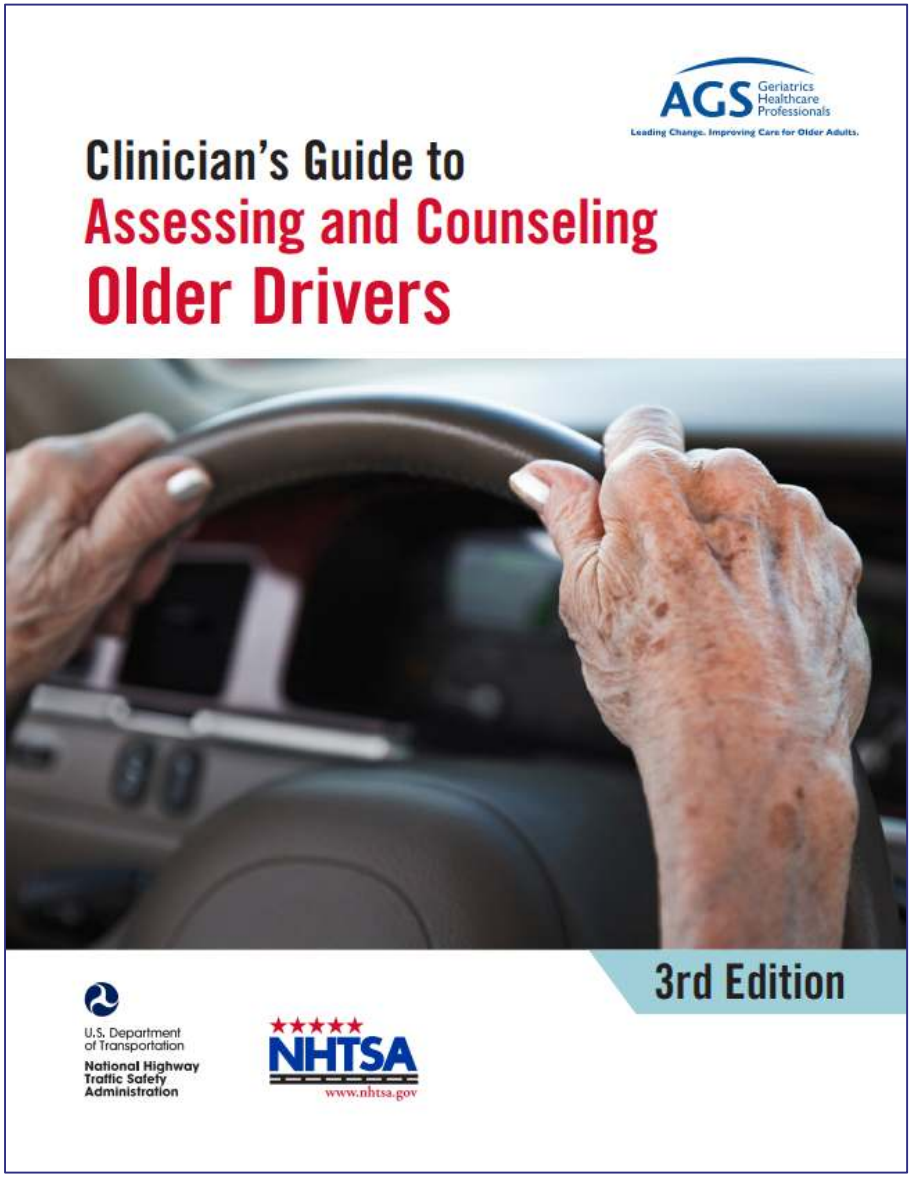
- https://psychiatryonline.org/doi/pdf/10.1176/appi.books.9780890426760

DRIVING ISSUES

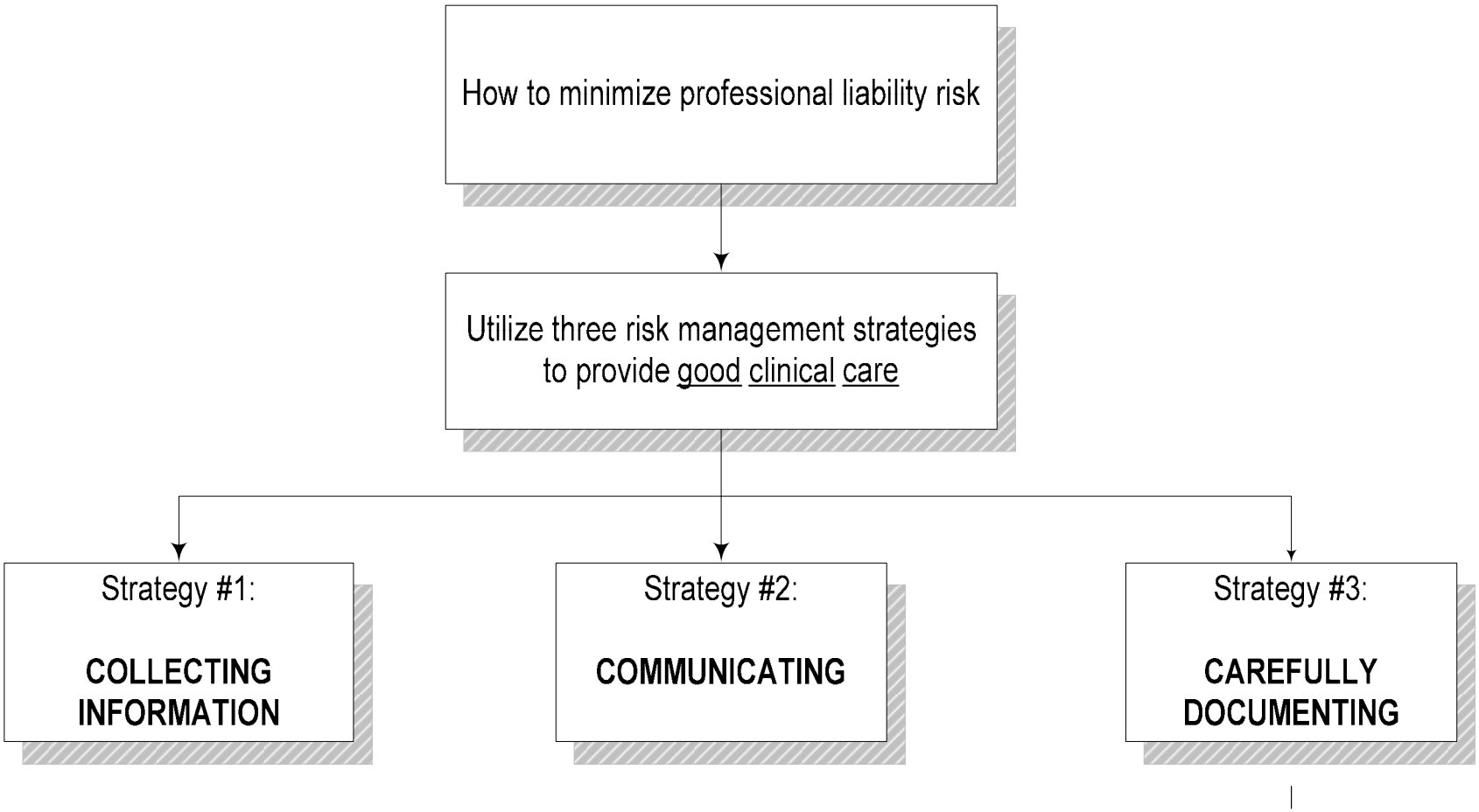
Know your state's statutes or regulations regarding the reporting of impaired drivers

DRIVING ISSUES

Consider other options before resorting to making a report about a patient's driving



www.nhtsa.gov/sites/nhtsa.dot.gov/files/812228_cliniciansguidetoolderdrivers.pdf



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

Strategy #1: COLLECT INFORMATION

- About the patient
  - History (including medication reconciliations)
  - Examination
  - Check the PMP
- About the medication
  - FDA.gov
- About treatment standards
  - APA assessment and treatment guidelines
  - AAFP
  - AAGP

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

Strategy #2: COMMUNICATE

- With patient
  - Risks and benefits
    - Falls
    - Adverse drug events related to somatic conditions
  - Driving concerns
- With others
  - Other prescribers and consultants
  - Significant others and caregivers

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

Strategy #3: CAREFULLY DOCUMENT

- Assessments performed
- Documents related to surrogate decision-makers, powers of attorney, psychiatric advance directives
- Consultations obtained
- Discussions of driving & fall concerns
- Reasoning behind prescribing decisions

CHILD & ADOLESCENT PSYCHIATRY

JUSTIN POPE, JD

Schools Face the Teen Cutting Problem

Cyberbullying on Social Media Linked to Teen Depression

CDC warns that Americans may be overmedicating youngest children with ADHD

There's a shortage of child psychiatrists, and kids are hurting

Suicide on Campus and the Pressure of Perfection

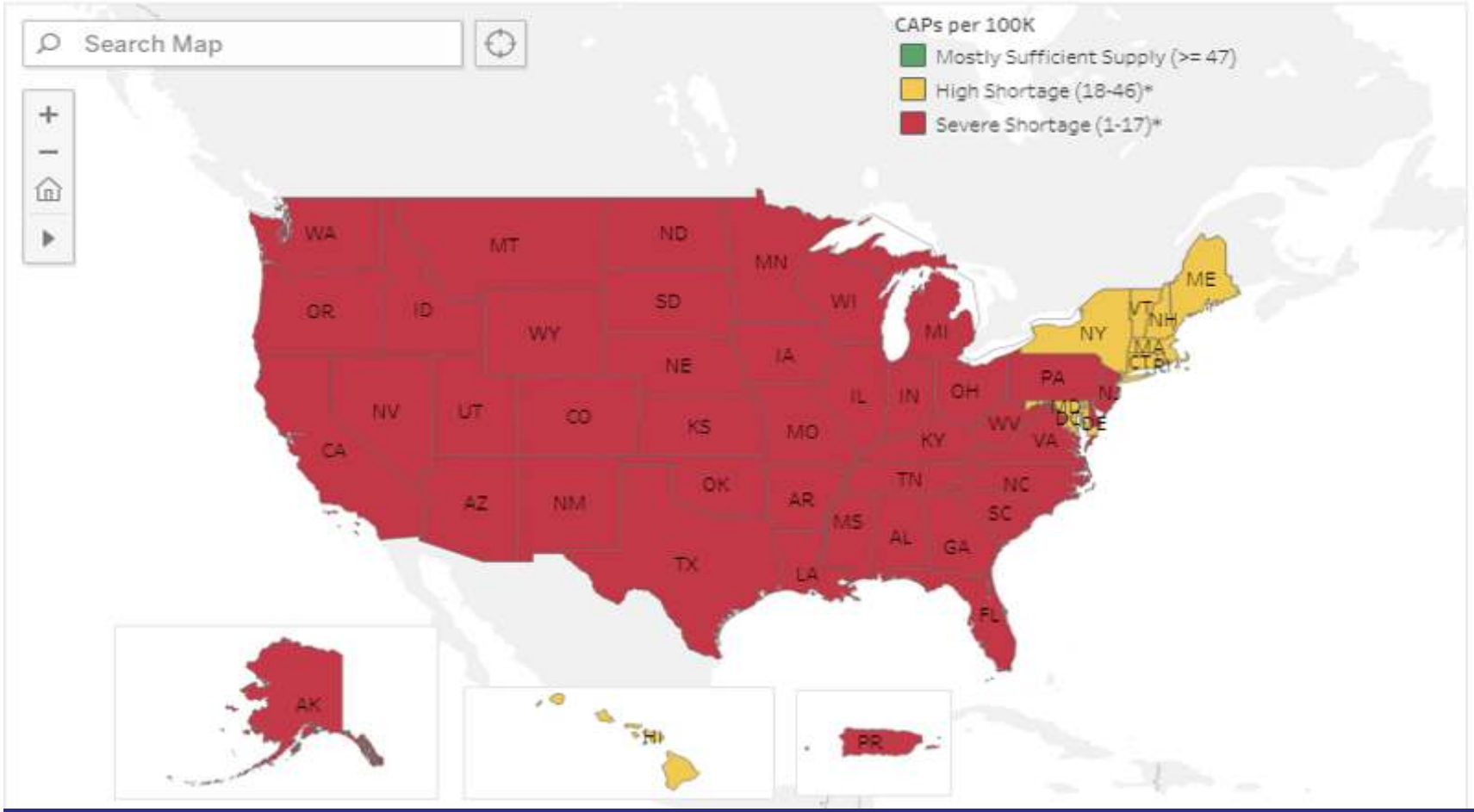
Teenagers, Medication and Suicide

Suicide Rates Climb In U.S., Especially Among Adolescent Girls

Still in a Crib, Yet Being Given Antipsychotics

Practicing Child and Adolescent Psychiatrists

Select a state for county population and workforce data



https://www.aacap.org/aacap/Advocacy/Federal_and_State_Initiatives/Workforce_Maps/Home.aspx
Accessed May 2019

WHAT WE WILL COVER

- An Overview of Professional Liability Exposure When Treating Child & Adolescent Patients

- Three Key Risk Management Strategies –
  - Collect Information
  - Communicate
  - Carefully Document

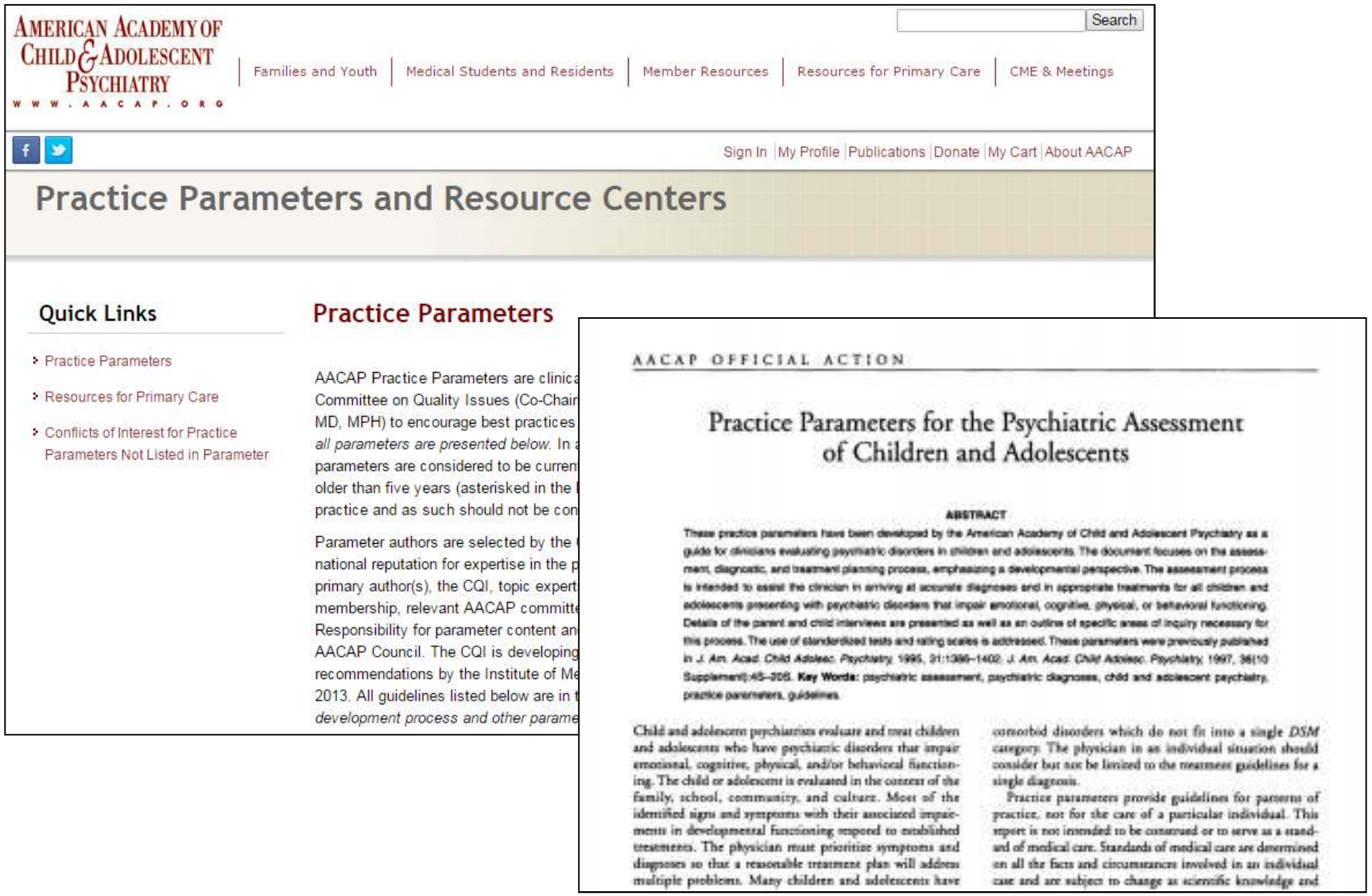
PROFESSIONAL LIABILITY EXPOSURE WHEN TREATING MINORS

ELEMENTS OF A LAWSUIT

- Duty of Care
  - The physician owed a duty 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)
- Proximate Cause
  - The patient's damages were a direct result of the physician's negligence

DETERMINING THE APPLICABLE STANDARD OF CARE

- Authoritative clinical guidelines
- Policies and guidelines from professional organizations
- Learned treatises
- Journal articles
- Research reports
- Accreditation standards
- Facility's own policies and procedures
- PDR recommendations
- Drug manufacturer recommendations
- Other items



www.jaacap.com/article/S0890-8567(09)62591-0/pdf
Accessed September 2015

Table 2

ADA Screening Guidelines for Patients on Second-Generation Antipsychotics

	Baseline	4 weeks	8 weeks	12 weeks	Annually
Personal & family history	X				X
Weight (BMI)	X	X	X	X	
Waist circumference	X				X
Blood pressure	X			X	X
Fasting plasma glucose	X			X	X
Fasting lipid profile (HDL, LDL, TG, total cholesterol)	X			X	

www.aacap.org/galleries/PracticeParameters/Atypical_Antipsychotic_Medications_Web.pdf
Accessed October 2015

‹ Telepsychiatry Toolkit Main

Child & Adolescent Telepsychiatry

In partnership with the American Academy of Child & Adolescent Psychiatry, APA developed this toolkit to address the issues unique to practicing telepsychiatry with children and adolescents. The mission of AACAP is to promote the healthy development of children, adolescents and families through advocacy, education and research, and to meet the professional needs of child and adolescent psychiatrists throughout their careers.

The Toolkit covers topics in telepsychiatry related to history, training, practice/clinical issues, reimbursement, and legal issues from leading child and adolescent psychiatrists.

History and Background

- Introduction to Child and Adolescent Telepsychiatry
- History of Child and Adolescent Telepsychiatry
- My Telemental Health Journey
- Evidence Base

Legal, Regulatory and Safety Issues

- Legal and Regulatory Issues
- Patient Safety
- Training in Child and Adolescent Telepsychiatry Fellowships

Setting Up Practice

- Return on Investment
- Technology-Specific Training Considerations

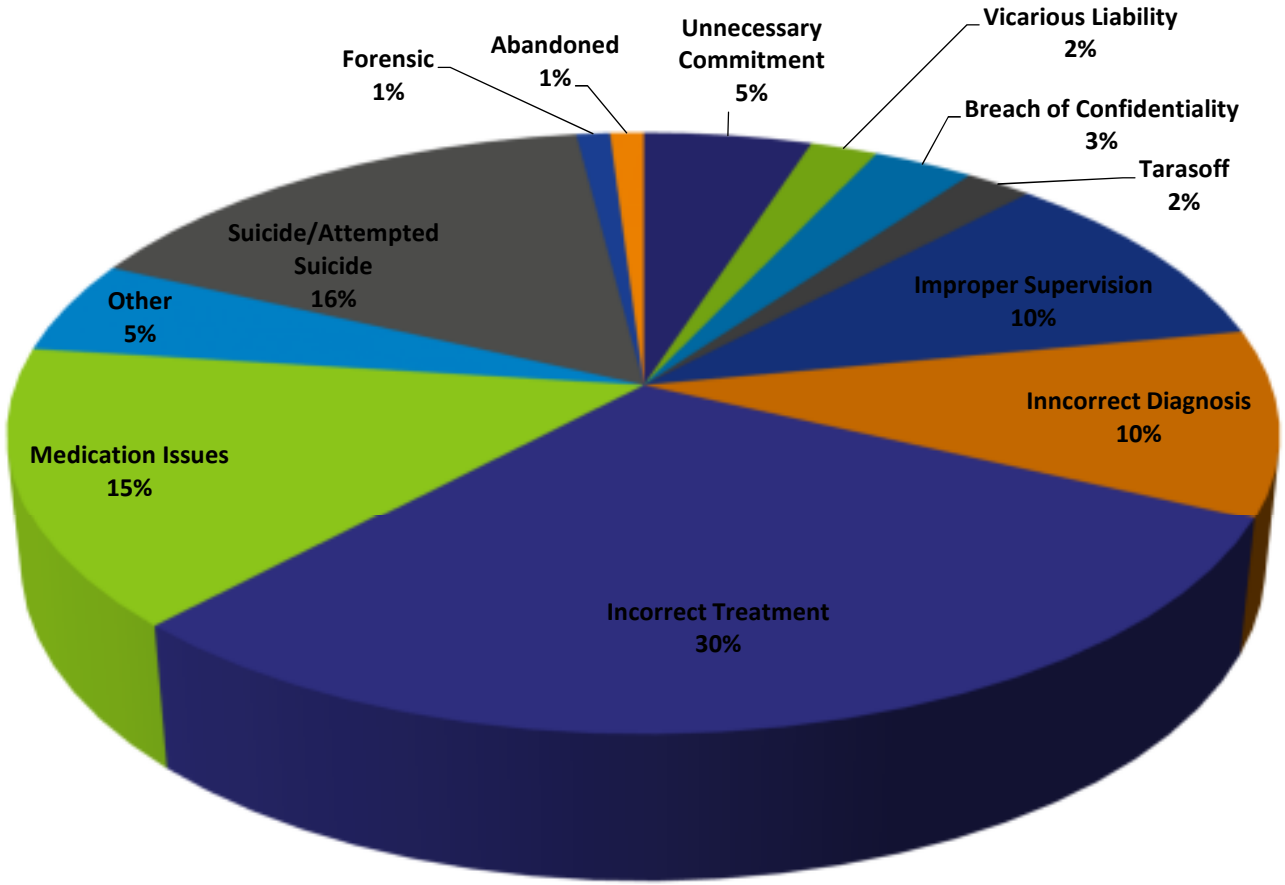
https://www.psychiatry.org/psychiatrists/practice/telepsychiatry/toolkit/child-adolescent
Accessed May 2019

GREATEST EXPOSURE

- Greatest Professional Liability Exposure

- When treating minor patients:
  - Patient suicide / attempted suicide
  - Psychopharmacology

THE PSYCHIATRISTS' PROGRAM
LAWSUITS INVOLVING MINOR PATIENTS
1986-2018
BY CAUSE OF LOSS



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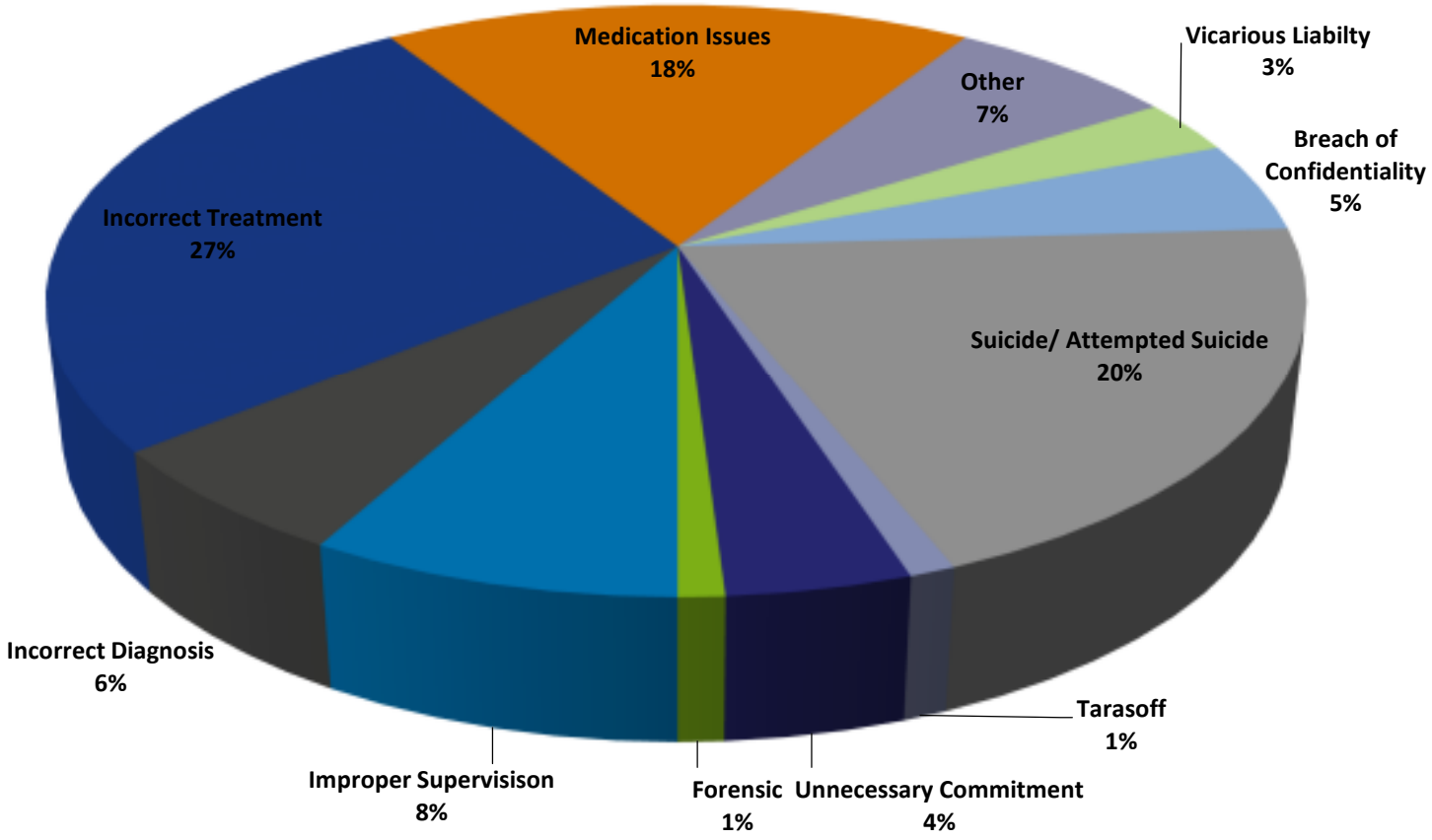

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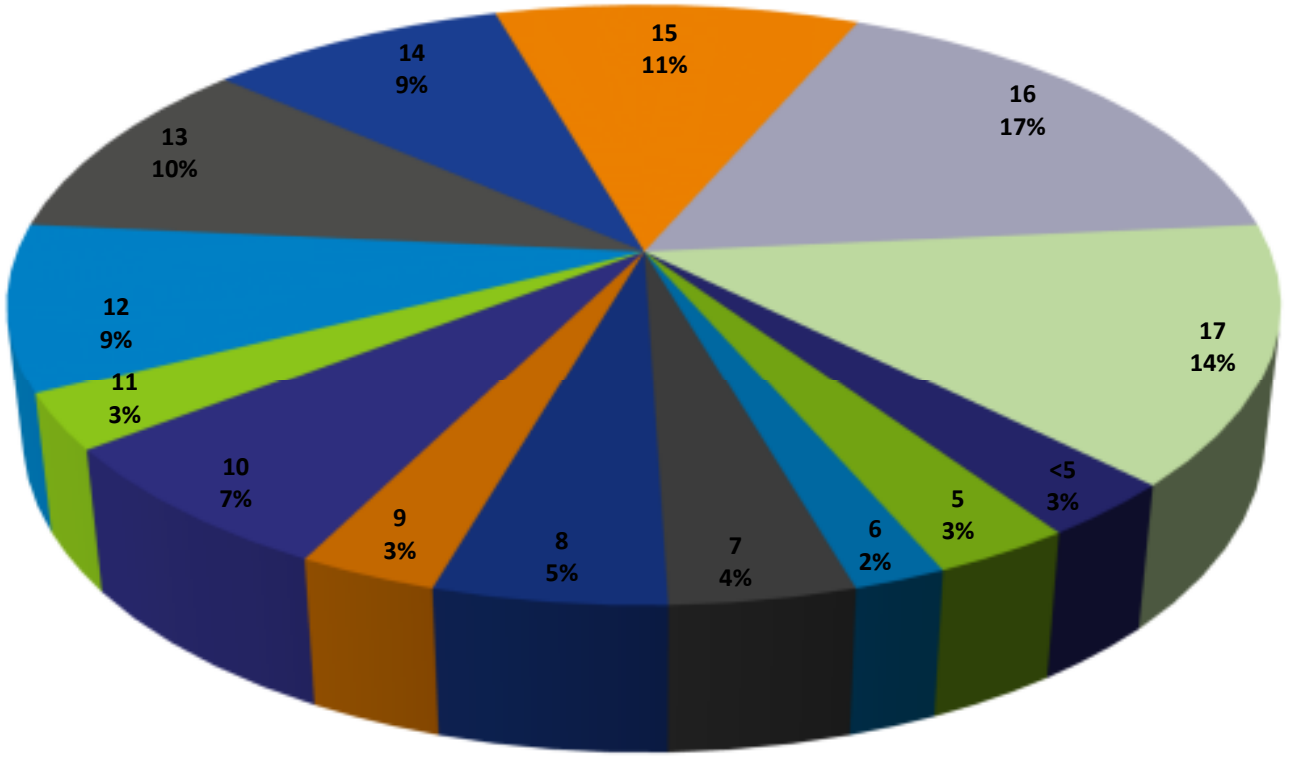

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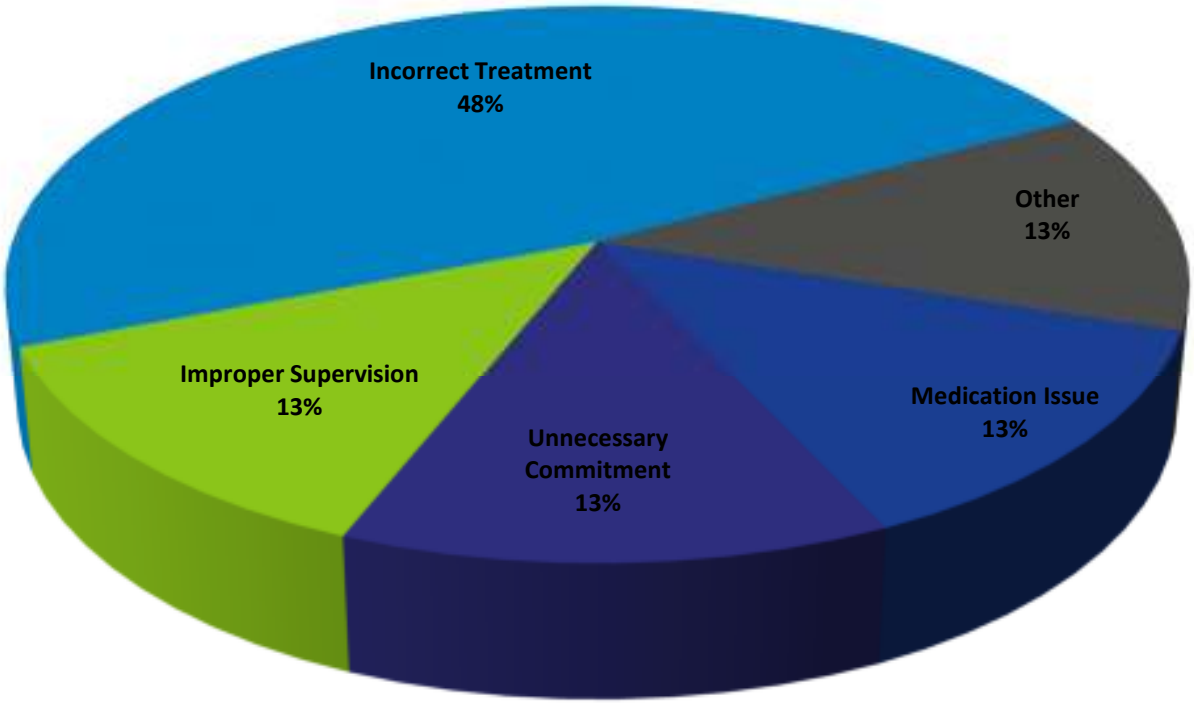

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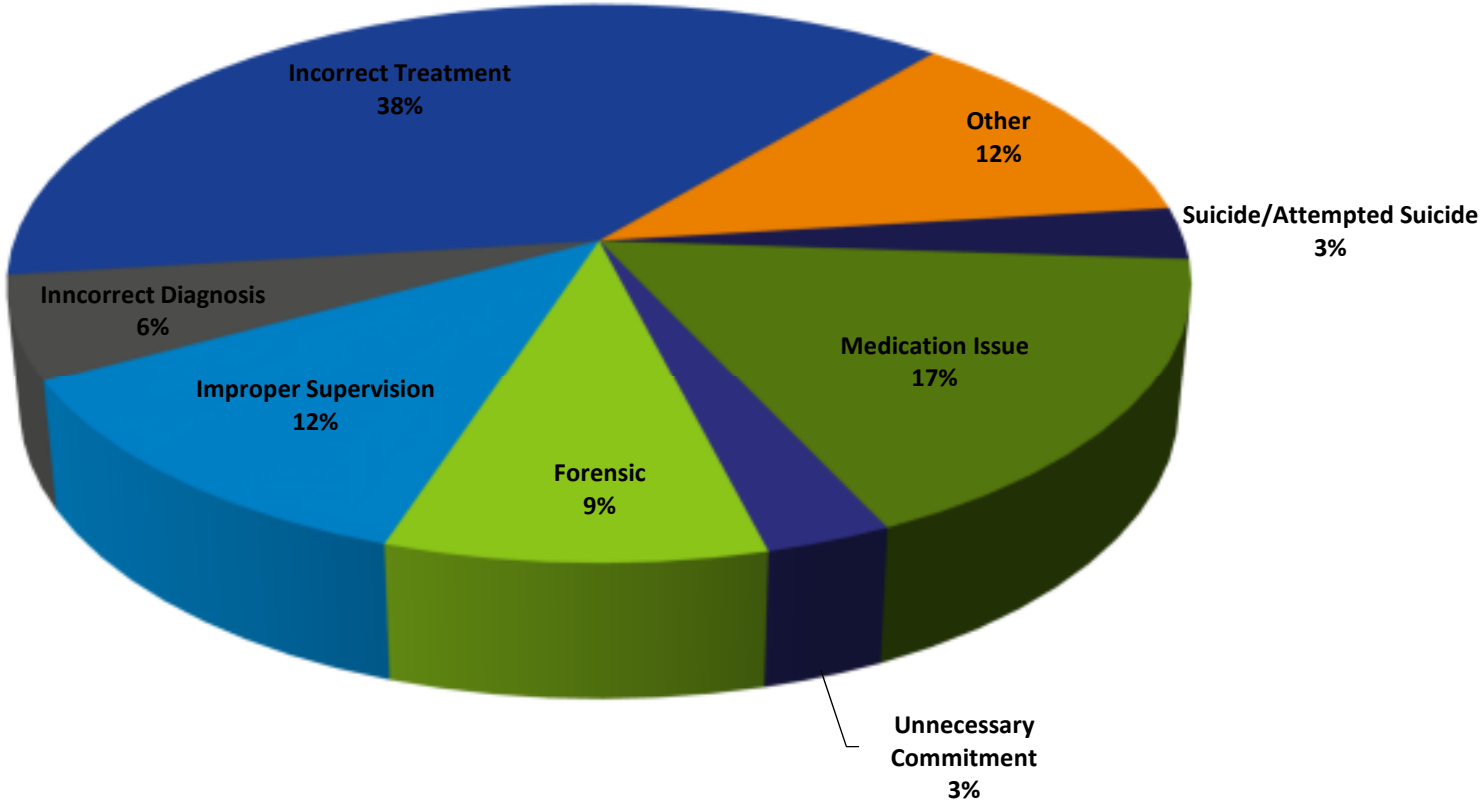

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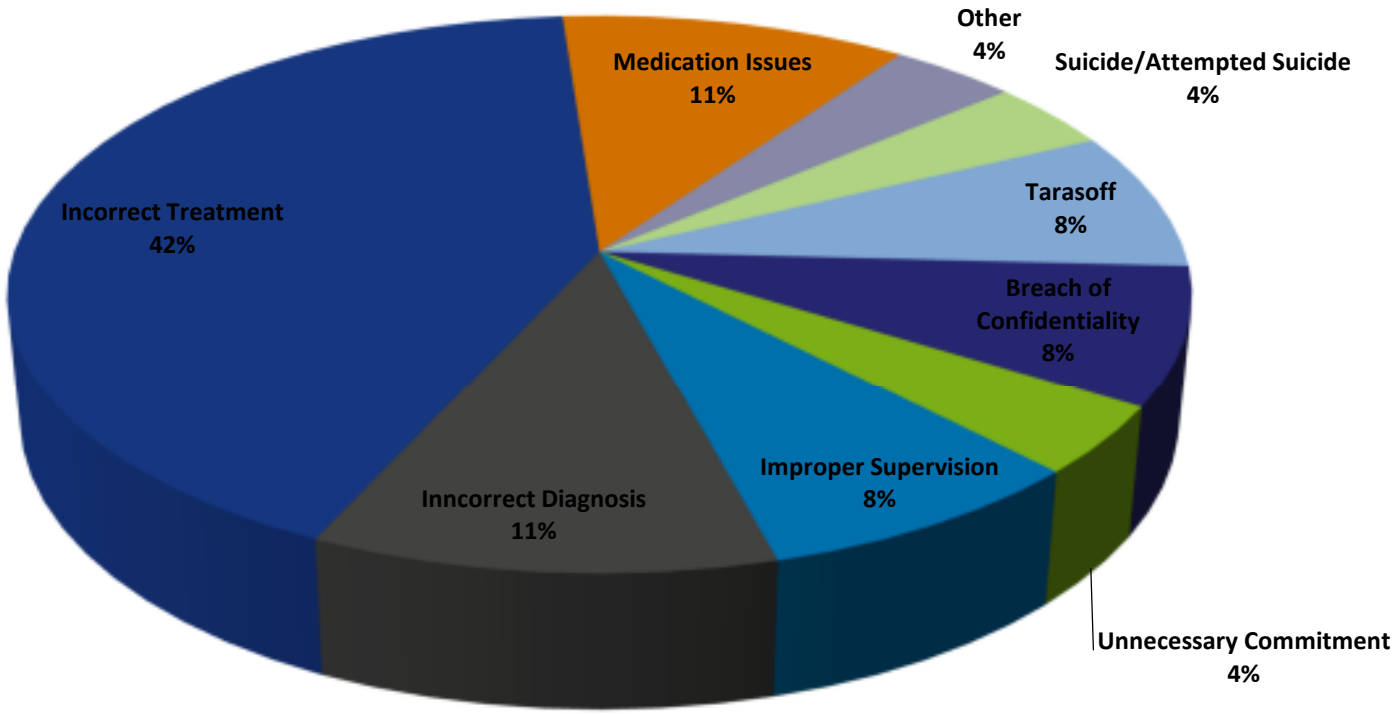

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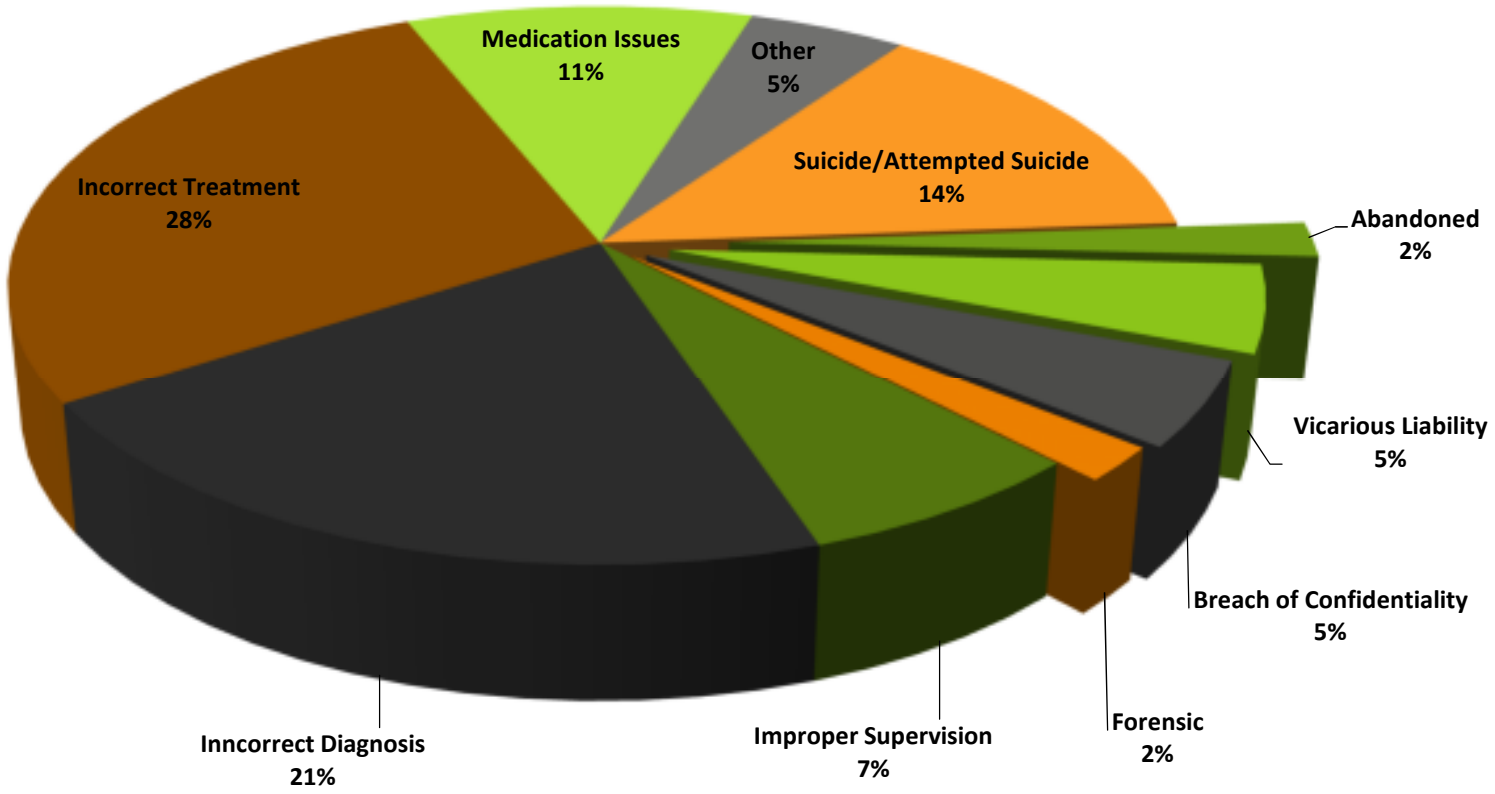

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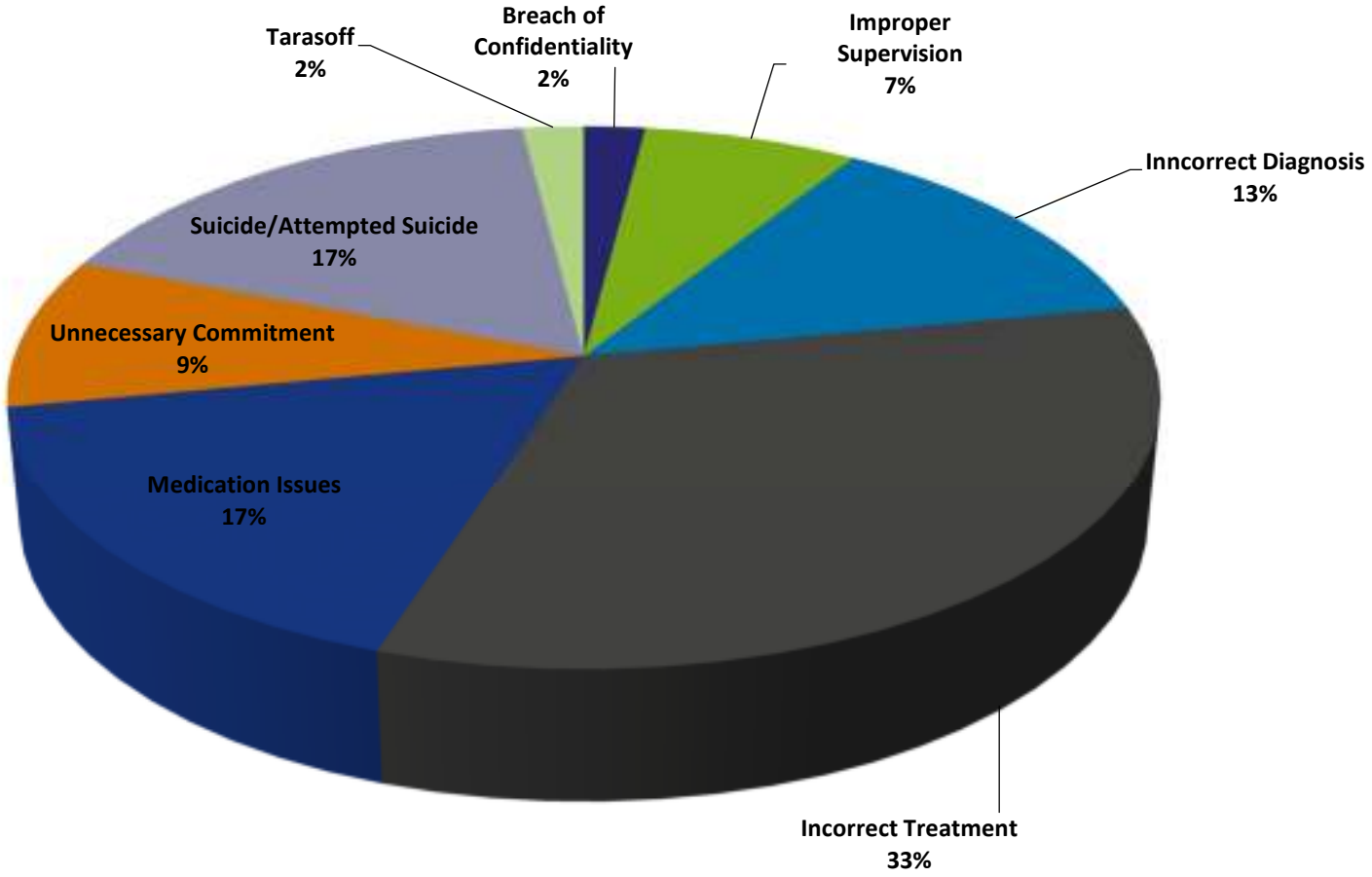

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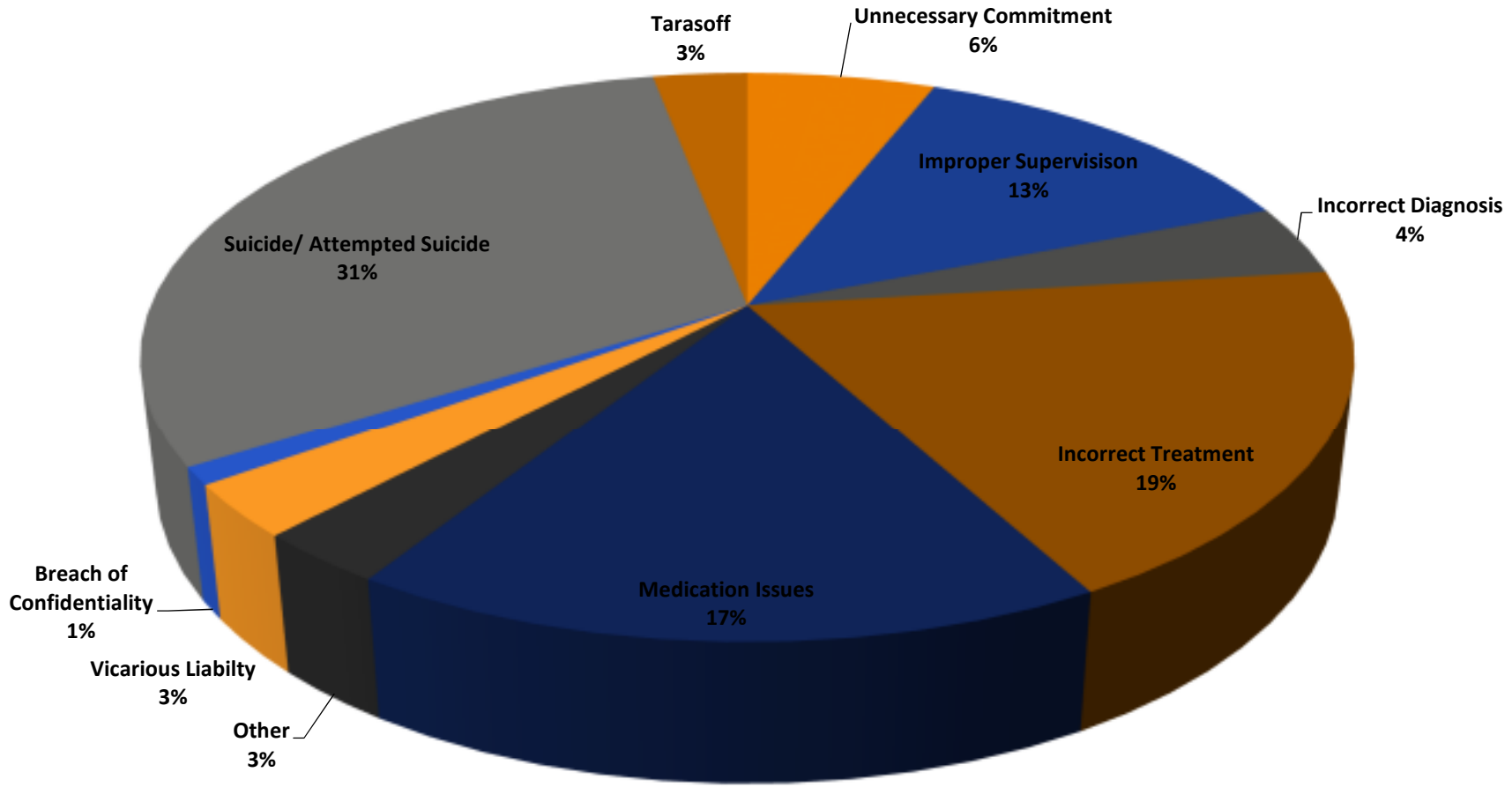

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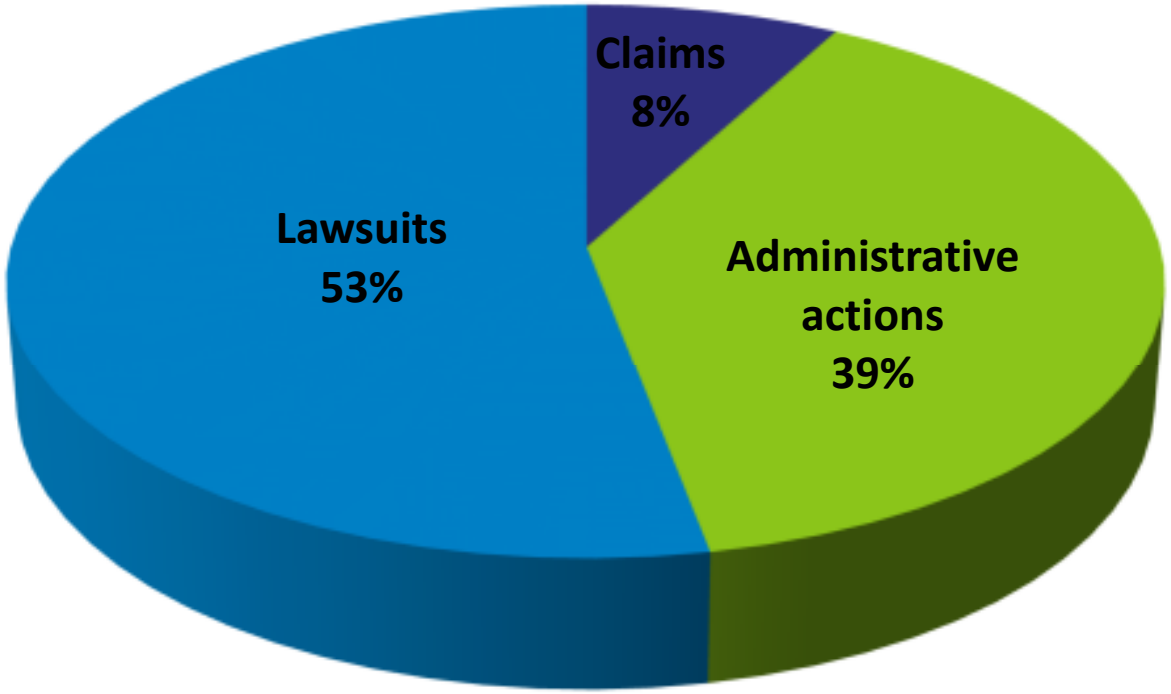
MINOR PATIENTS
(1986-2018)



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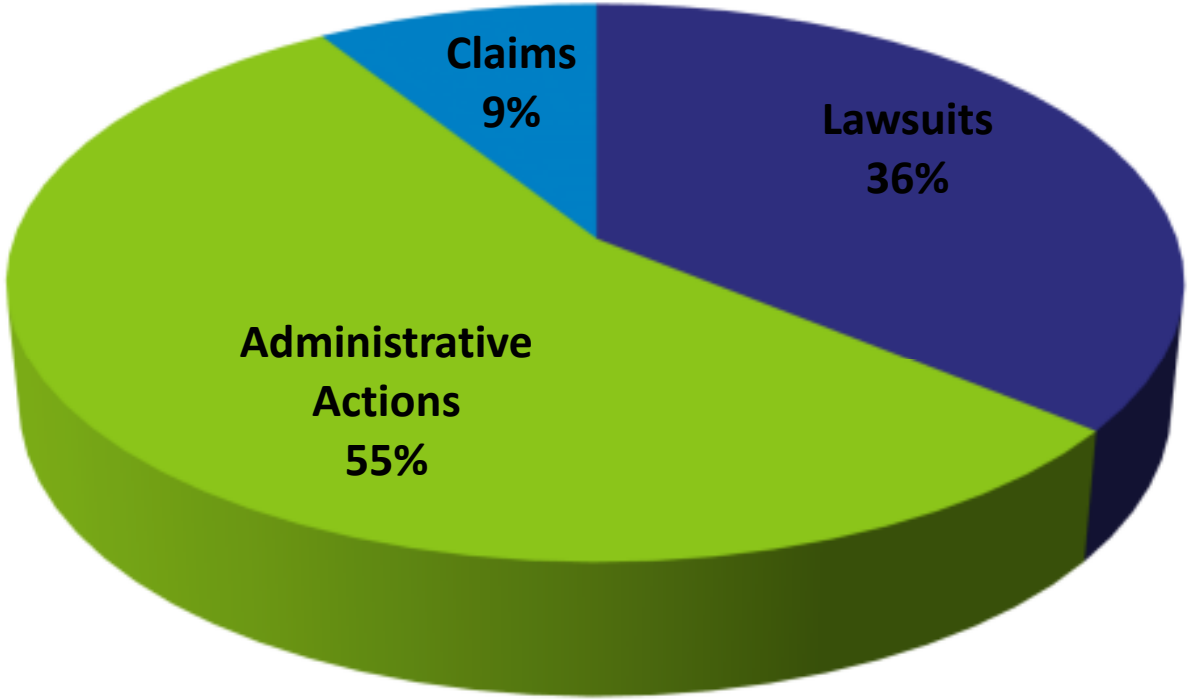
THE PSYCHIATRISTS' PROGRAM
LAWSUITS, CLAIMS, AND ADMINISTRATIVE ACTIONS
MINOR PATIENTS
(2004-2018)



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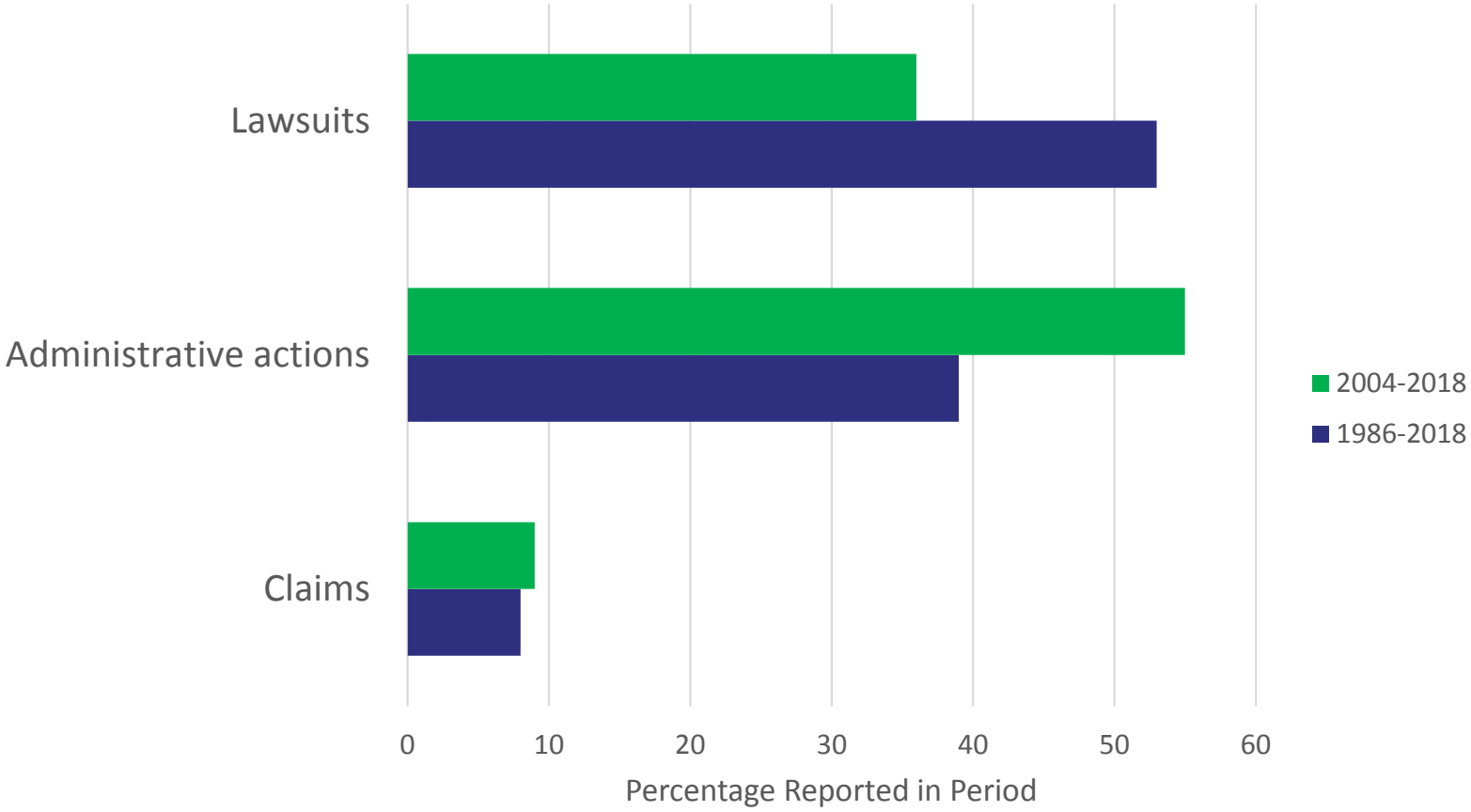
THE PSYCHIATRISTS' PROGRAM
COMPARING LAWSUITS, CLAIMS, AND ADMINISTRATIVE ACTIONS
MINOR PATIENTS



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PRMS DATA: ADMINISTRATIVE ACTIONS

Overlapping themes:

- Divorced parents
- Psychopharmacology
- Child abuse
- Termination

ADDITIONAL LIABILITY RISK WHEN TREATING MINORS

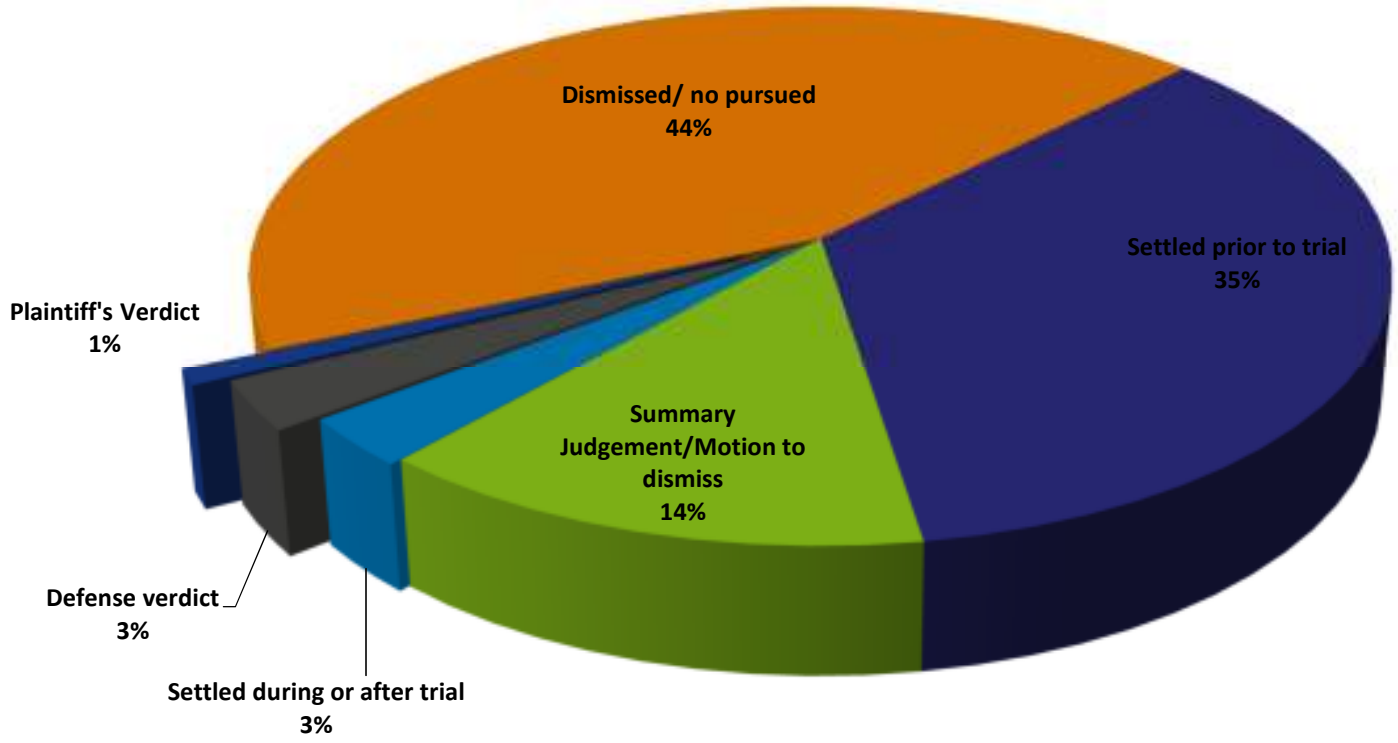
Unique characteristics of patient population:

- Off-label prescribing
- Many parties can complain
- Statute of limitations
- Vulnerable population

THINGS TO KEEP IN MIND

- Payouts are lower for minor patients' cases vs. adult patients
- Psychiatry – one of the least often sued medical specialties

THE PSYCHIATRISTS' PROGRAM
LAWSUITS INVOLVING MINOR PATIENTS
1986-2018
BY DISPOSITION



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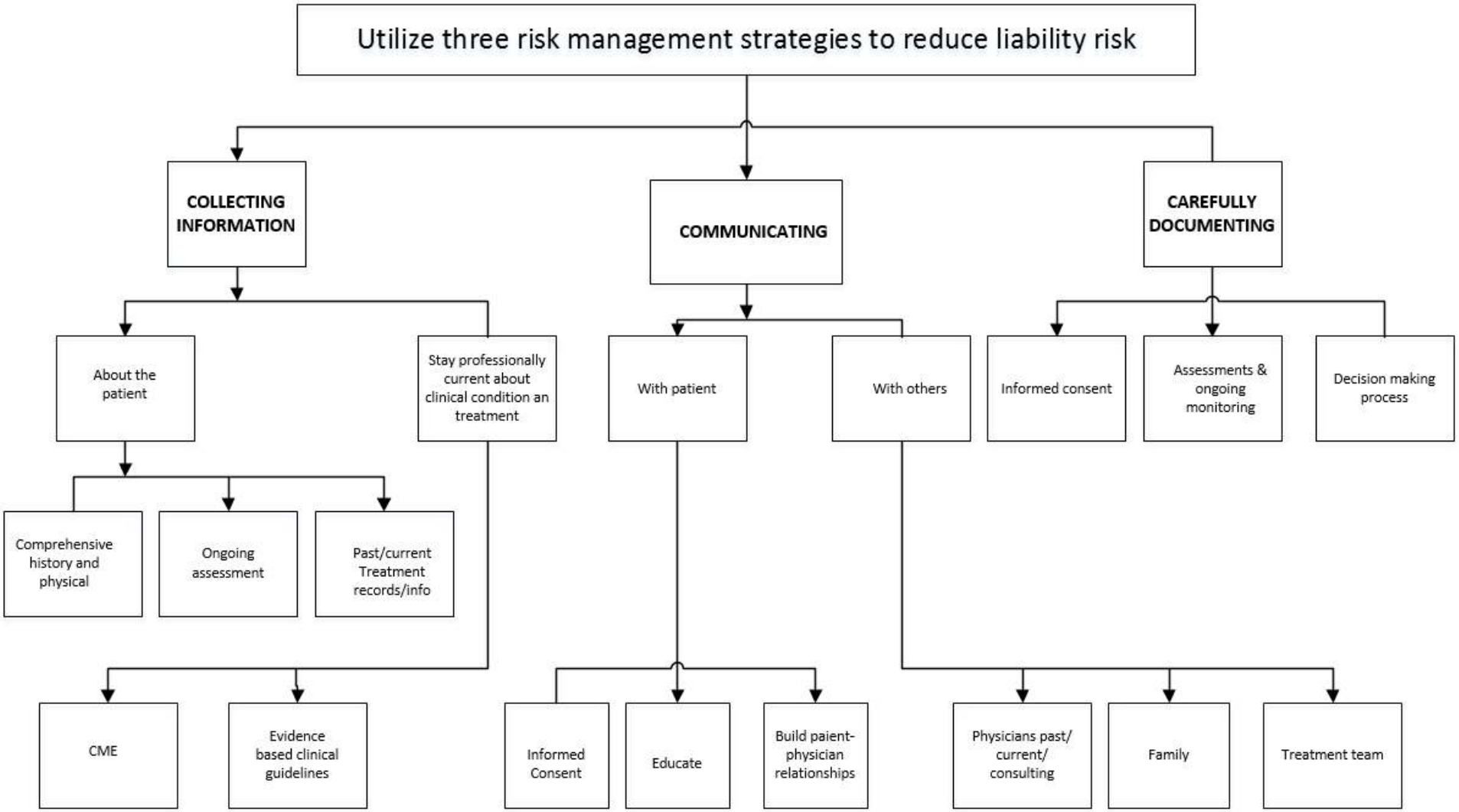
THREE KEY RISK MANAGEMENT STRATEGIES WHEN TREATING MINORS

THREE KEY RISK MANAGEMENT STRATEGIES (THE THREE Cs)

1. Collect Information
2. Communicate
3. Carefully Document

3 Cs of RISK MANAGEMENT



RISK MANAGEMENT STRATEGY #1: COLLECTING INFORMATION

COLLECTING INFORMATION – ABOUT THE PATIENT

- Assess patients at significant points in treatment
- Assessment is ongoing
  - Consider possibility of comorbid conditions
    - Substance abuse
    - Medical conditions
- Obtain prior records / document efforts
- Collateral information from family and others
- Inquire about access to weapons

State of California Department of Justice

XAVIER BECERRA
Attorney General

Search

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HOME ABOUT MEDIA CAREERS REGULATIONS RESOURCES PROGRAMS CONTACT

Controlled Substance Utilization Review and Evaluation System

Home / PDMP / CURES / *Controlled Substance Utilization Review and Evaluation Syste...*

CURES 2.0

CURES Certification

Pursuant to Section 11165.4 (e) of the Health and Safety Code, the Department of Justice certifies that, as of April 2, 2018, the CURES database is ready for statewide use and that the Department of Justice has adequate staff, user support, and education. **Mandatory CURES consultation becomes effective on October 2, 2018**.

PDMP / CURES

PDMP / CURES Home

General FAQs

CURES 2.0 Registration

CURES Login

Publications and Training

CURES Statistics

AB40: CURES Information Exchange Web Service (IEWS)

California Security Printer Program

https://oag.ca.gov/cures

Marijuana and Teens

No. 106; Updated May 2018

Many teenagers try marijuana and some use it regularly. Teenage marijuana use is at its highest level in 30 years, and today's teens are more likely to use marijuana than tobacco. Many states allow recreational use of marijuana in adults ages 21 and over. Recreational marijuana use by children and teenagers is not legal in anywhere in the United States. Today's marijuana plants are grown differently than in the past and can contain two to three times more tetrahydrocannabinol (THC), the ingredient that makes people high. The ingredient of the marijuana plant thought to have most medical benefits, cannabidiol (CBD), has not increased and remains at about 1%.

There are many ways people can use marijuana. This can make it harder for parents to watch for use in their child. These include:

- Smoking the dried plant (buds and flowers) in a rolled cigarette (joint), pipe, or bong
- Smoking liquid or wax marijuana in an electronic cigarette, also known as vaping
- Eating "edibles" which are baked goods and candies containing marijuana products
- Drinking beverages containing marijuana products
- Using oils and tinctures that can be applied to the skin

Other names used to describe marijuana include weed, pot, spliffs, or the name of the strain of the plant. There are also synthetic (man-made) marijuana-like drugs such as "K2" and "Spice." These drugs are different from marijuana and are more dangerous.

The New York Times

Addicted to Vaped Nicotine, Teenagers Have No Clear Path to Quitting

Dr. Susanne Tanski, a pediatrics professor at Dartmouth, holding pieces of a vape pen that can be worn on a lanyard. Elizabeth Frantz for The New York Times

https://www.nytimes.com/2018/12/18/health/vaping-nicotine-teenagers.html

COLLECTING INFORMATION – ABOUT THE PATIENT IN THE DIGITAL AGE

Consider what patients can do in the digital age:

- Social Networking
- Bullying and being bullied
- Online pornography
- Sexting
- Posting nude photos
- Gambling
- Violent gaming
- Searching for info on dangerous behaviors

The New York Times

Think You're Discreet Online? Think Again

Thanks to "data inference" technology, companies know more about you than you disclose.

By Zeynep Tufekci

Dr. Tufekci is a professor of information science who specializes in the social effects of technology.

April 21, 2019

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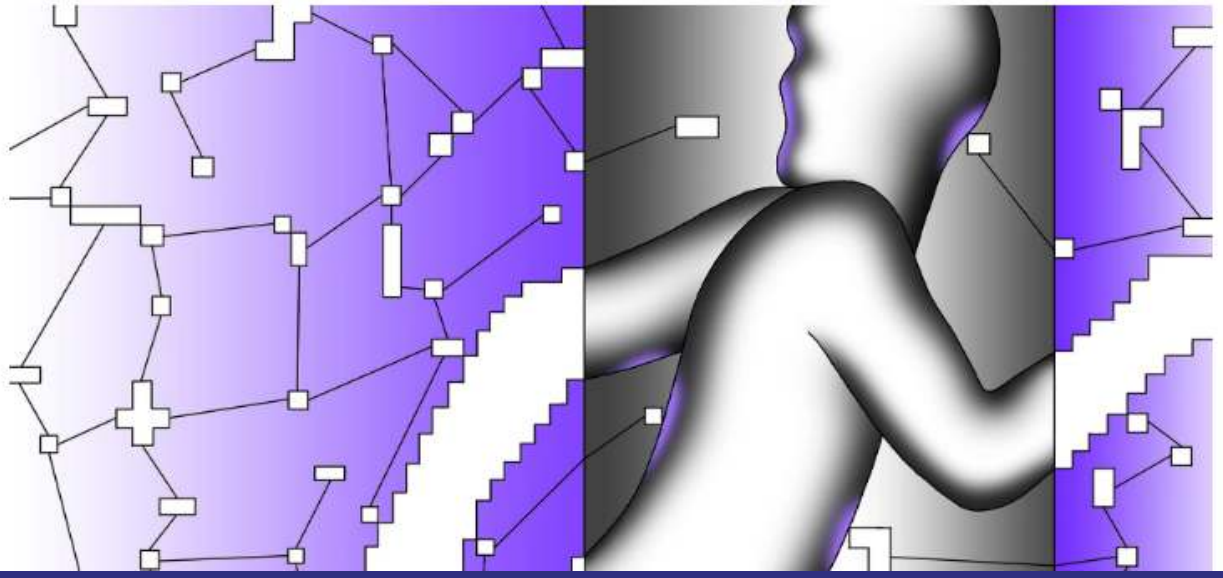

https://www.nytimes.com/2019/04/21/opinion/computational-inference.html

THEY CAN BULLY AND BE BULLIED ONLINE

Bullying Found to Increase Risk for Adolescent Suicide Attempts Worldwide

LINDA M. RICHMOND

Published Online: 2 May 2019 | https://doi.org/10.1176/appi.pn.2019.5a17

Psychiatrists should consider asking their adolescent patients about whether they are being bullied.

Adolescents who are bullied have a threefold higher risk of suicide attempts globally, according to a study published in March in the *Journal of the American Academy of Child & Adolescent Psychiatry*. The findings emphasize the importance of screening youth for exposure to bullying, assessing suicidality in youth who have been bullied, as well as enhancing youth coping and problem-solving skills.

"Bullying victimization may be an important risk factor of suicide attempts among adolescents globally," wrote Ai Koyanagi, M.D., Ph.D., of the Research and Development Unit at the Universitat de Barcelona in Barcelona, Spain, and the Centro de Investigación Biomédica en Red de Salud Mental in Madrid, Spain, and colleagues. "Thus, there is an urgent need to implement effective and evidence-based interventions to address bullying in order to prevent suicides and suicide attempts among adolescents worldwide."

Self-harm is the third-leading cause of death among adolescents worldwide, resulting in about 67,000 deaths a year, according to the World Health Organization. For this

Instagram Has a Massive Harassment Problem

The platform has cast itself as the internet's kindest place. But users argue harassment is rampant, and employees say efforts to stem it aren't funded well or prioritized.

Share Tweet ···

TEXT SIZE − +

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Email SIGN UP

WHEN Brandon Farbstein first joined Instagram in 2014, he was 14 and optimistic. Farbstein was born with a rare form of dwarfism, and he wanted to use the photo-sharing site to educate people about his condition—to, as he told me, "show people a glimpse into my life and inspire people."

Soon enough, though, the hateful messages started coming: death threats, expletive-laden comments about his appearance, worse. A meme page put his

https://www.theatlantic.com/technology/archive/2018/10/instagram-has-massive-harassment-problem/572890/

THEY CAN ENGAGE IN SEXUAL ACTIVITIES ONLINE

ONLINE SEXUAL ACTIVITY STATISTICS

- Pornography –
  - The largest group of internet pornography consumers is children ages 12-17.
  - 90% of kids ages 8-16 have seen online pornography.
- Sexting –
  - 37% of teen girls, 40% of teen boys say they have sexted.
  - 48% of teens say they received sexts.
- Posting –
  - 22% of teenage girls, 18% of teen boys report posting nude or semi-nude photos or videos of themselves online.

www.guardchild.com/statistics/

ONLINE SEXUAL ACTIVITY STATISTICS (CONT.)

- Solicitation –
  - Law enforcement estimates that more than 50,000 sexual predators are online at any given moment.
  - 69% of teens regularly receive online communications from strangers and don't tell a parent or caretaker.
  - 20% of teenaged internet users have been the target of unwanted sexual solicitation.
  - 1 in 33 youth received an aggressive sexual solicitation (meaning predator asked to meet youth, called youth, or sent youth correspondence, money, or gifts.

www.guardchild.com/statistics/

THEY CAN MASK THEIR IDENTITIES

GENERAL OBSERVATIONS

The virtual social world:

- Difficult to determine true identities
- You can be whomever you want
- “Online disinhibition effect”

ONLINE DISINHIBITION EFFECT

"Loosening / abandonment of social restrictions and inhibitions that would otherwise be present in normal face-to-face interaction during interactions with others on the internet."

Suler J. The online disinhibition effect. CyberPsychology & Behavior 7(3):321-326

THEY CAN SEARCH FOR INFORMATION ON DANGEROUS BEHAVIORS

Anorexia is a lifestyle, not a disease.

10/01/2012

How are you all doing?

Labels: Diary, Info

We'll the tittle says it all...
I'm just wondering, how are you all doing?
Are there already some buddy matches made by yourself?
And how are you holding up?

I'm extremely busy by answering your emails, but I love to do so. And same time trying to make something of the forum, which does excist, but I don't understand it yet. But we are getting closer every day.

The safety settings are back to what they were, cause there was no way to keep up for me with all the busy traffic. What still remains is that all reactions have to be moderated by me first.

I'm also busy matching you all as buddy's together, looking for who I think are going to be good couples, but you all understand that its all a lot of work I hope.

Just know, I'm working a daytime job for ya'll. And I do it with all my love!

Love Jade

Thin Commandments

1) If you aren't thin, you aren't attractive
2) Being thin is more important than being healthy
3) You must but clotes, cut your hair, take laxatives, anything to make yourself look thinner
4) Thou shall not eat without feeling guilty
5) Thou shall not eat fattening food withoud punishing afterwards
6) Thou shall count calories and restrict intake accordingly
7) What the scale says is the most important thing
8) Losing weight is good, gaining weight is bad
9) You can never be to thin
10) Being thin and not eating are signs of true will power and succes.

A VIRTUAL PATH TO SUICIDE / Depressed student killed herself with help from online discussion group

Julia Scheeres, Special to The Chronicle Published 4:00 am PDT, Sunday, June 8, 2003

Photo: HANDOUT

www.sfgate.com/news/article/a-virtual-path-to-suicide-depressed-student-2611315.php

BBC Trending

Blue Whale: What is the truth behind an online 'suicide challenge'?

By Ant Adeane
BBC Trending

13 January 2019

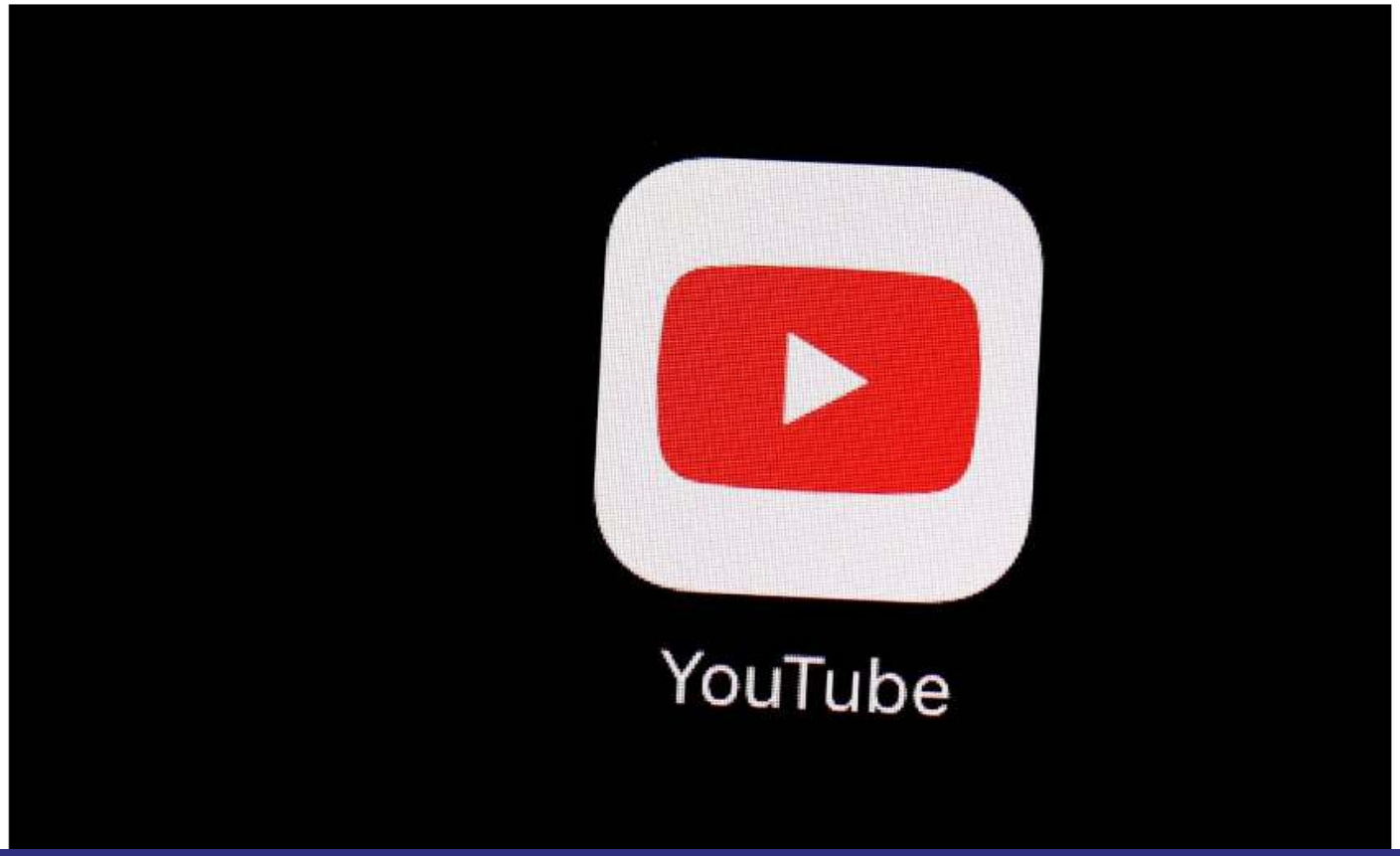
Share

The "Blue Whale challenge" was reported to be an online "suicide game" aimed at teenagers which set 50 tasks over 50 days. The challenge was

https://www.bbc.com/news/blogs-trending-46505722

Internet Culture

A pediatrician exposes suicide tips for children hidden in videos on YouTube and YouTube Kids



https://www.washingtonpost.com/technology/2019/02/24/pediatrician-exposes-suicide-tips-children-hidden-videos-youtube-youtube-kids/?utm_term=.47fd3a341afc

Quick Links

- Related Websites
- Annual Reports
- About AACAP
- Employment at AACAP
- Regional Organizations
- Contact Us
- AACAP History

AACAP Transparency and Disclosures

AACAP Releases 13 Reason Why Resources

Washington, DC, May 18, 2018 – Netflix released the second season of 13 Reasons Why today, and the American Academy of Child and Adolescent Psychiatry (AACAP) compiled resources in response. Season one controversially and graphically covered the topics of suicide, bullying, violence, and more. While it helped begin much needed conversations on these important topics, we support including mental health, parental and adult guidance, as well as how to seek help in these discussions for more positive responses. For this reason, we offer the following resources in hopes of helping children and families at the time of season two's release.

***13 Reasons Why* Resources**

AACAP Resources:

- Depression Resource Center
- Suicide Resource Center
- Bullying Resource Center
- Substance Use Resource Center
- Responding to Gun Violence

AACAP Facts for Families:

https://www.aacap.org/AACAP/Press/Press_Releases/2018/AACAP_Releases_13_Reasons_Why_Resources.aspx

Association Between the Release of Netflix's *13 Reasons Why* and Suicide Rates in the United States: An Interrupted Times Series Analysis

Jeffrey A. Bridge, PhD[a,b,*], Joel B. Greenhouse, PhD[d], Donna Ruch, PhD[a], Jack Stevens, PhD[a,b], John Ackerman, PhD[b,c], Arielle H. Sheftall, PhD[a,b], Lisa M. Horowitz, PhD, MPH[e], Kelly J. Kelleher, MD[a,b], John V. Campo, MD[f]

PlumX Metrics

DOI: https://doi.org/10.1016/j.jaac.2019.04.020

Article Info

Abstract | Full Text | Images | References | Supplemental Materials

Objective

To estimate the association between the release of the Netflix series *13 Reasons Why* and suicide rates in the United States.

Method

Using segmented quasi-Poisson regression and Holt-Winters forecasting models, we assessed monthly rates of suicide among individuals aged 10 to 64 years grouped into 3 age categories (10–17, 18–29, and 30–64 years) between January 1, 2013, and December 31, 2017, before and after the release of *13 Reasons Why* on March 31, 2017. We also assessed the impact of the show's release on a control outcome, homicide deaths.

https://www.jaacap.org/article/S0890-8567(19)30288-6/fulltext

AMERICAN ACADEMY OF CHILD & ADOLESCENT PSYCHIATRY
WWW.AACAP.ORG

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Quick Links

- Practice Parameters
- Resources for Primary Care

Conflicts of Interest for Practice Parameters Not Listed in Parameter

Parameters, Updates, and Guidelines

BREAKING NEWS!

For over 25 years, the AACAP Committee on Quality Issues (CQI) has been charged with the development of a series of documents intended to inform clinical practice in child and adolescent psychiatry. Over the next few years, the original series – known as **Practice Parameters** – will be phased out and replaced by two new series of documents – known as **Clinical Updates and Clinical Practice Guidelines**. The following sections will present the current status of the Practice Parameters as well as describe the two new series of documents.

AACAP PRACTICE PARAMETERS

Practice Parameters, authored by individual AACAP experts, addressed a broad range of topics in child and adolescent psychiatry and behavioral health. Since their inception in 1991, more than 60 Practice Parameters have been published as AACAP *Official Actions* in the *Journal of the American Academy of Child and Adolescent Psychiatry*. The Practice Parameter development process can be reviewed at Instructions for Authors for the Development of AACAP Practice Parameters.

https://www.aacap.org/aacap/resources_for_primary_care/practice_parameters_and_resource_centers/practice_parameters.aspx

RISK MANAGEMENT STRATEGY #2: COMMUNICATE

COMMUNICATION

- With patients
- With parents
- With other treatment providers

COMMUNICATING – WITH PATIENTS AND PARENTS

- Informed Consent
- Minor's Confidentiality vs Parent's Right to Know
- Ongoing Assessment
- Improving the Conversation with Minors

CONSENT

General Rule

- < 18 incompetent to consent
- Parent or legal guardian
- No legal authority = NO Consent

CONSENT VARIES ACROSS STATES

MINOR'S ASSENT TO TREATMENT

American Academy of Child and Adolescent Psychiatry Code of Ethics, Principle IV: Assent and Consent (Autonomy)

"Guardians are responsible for the health and welfare of their children. Children and adolescents, however, should play a role in determining the services they receive and their participation in treatments to the extent of their capacities to understand options and act rationally. The right of assent to or dissent from treatment belongs to the individual child or adolescent of minor age. ***The child and adolescent psychiatrist shall, whenever reasonably possible, obtain the assent of the minor and the consent of the legal guardian prior to engaging in actions involving the child or adolescent."***

CONSENT

Risk Management Tips:

- Require parent/guardian at first appointment
- If guardian, obtain proof
- Signed authorization for other caregiver
- Agreement as to when parents must attend
- Communication re: meds

CONSENT

Children of Divorced Parents

- Obtain custody agreement or divorce decree!!!!
- Consider involving other parent
- Involvement of other caregivers

COMMON SCENARIO – DISAGREEMENT OVER TREATMENT

I am treating the child of a divorced couple. Per the divorce decree, each parent has equal custody and decision-making authority with regard to treatment. The parents disagree as to whether the child should be put on medication. What should I do?

CONSENT - OFF-LABEL PRESCRIBING

- Should be part of informed consent discussion.
- Consider:
  - Scientific basis
  - Sound medical evidence

CONSENT -
MEDICATION RESOURCES

ParentsMedGuide.org:

Medication guides

- ADHD
- Depression
- Bipolar Disorder

Minors' Confidentiality vs. Parents' Right to Know

Published on May 25, 2016

Donna Vanderpool, MBA, JD | Follow
VP, Risk Management at PRM...

12 0 0

One of the more complicated confidentiality issues involves a minor patient's right to confidentiality versus the parents' right to know what is going on in their child's treatment. There are at least these three competing interests:

The ethical piece: To the extent possible, minors should be accorded the same confidentiality rights as adults. From AACAP's code of ethics:

"Respect for the patient's privacy is of great importance to the establishment and maintenance of that trust. Thus the child or adolescent's right to privacy of communication is essential in the practice of child and adolescent psychiatry. Certainty that their verbal expressions are protected as confidential allows minor patients to reveal their feelings and thoughts to the clinicians providing care, with the assurance that the contents of their discussions will not be communicated to others without their permission…"

The clinical piece: Minors need treatment, but will not get treatment without confidentiality, or if they get treatment, without confidentiality, the diagnosis may not be accurate, which can lead to ineffective or even harmful treatment.

And the legal piece: Parents generally have the right to information about treatment as well as the right to access the records of their minor children.

MINORS' CONFIDENTIALITY VS. PARENTS' RIGHT TO KNOW

Three Competing Interests:

- Ethical – AACAP Code of Ethics
- Clinical – Confidentiality necessary for treatment.
- Legal – Parents generally have right to access information.

MINORS' CONFIDENTIALITY VS. PARENTS' RIGHT TO KNOW

Key Concepts -

1. Manage expectations of all parties.
2. There are exceptions to confidentiality.
3. Even if they say they won't, parents can always change their minds and demand a copy of your record.
4. With few exceptions, parents generally have the right to access the record of their minor child.
5. Document knowing that the record may have to be released to the parent(s).
6. What you believe is the "right" approach may be considered the "wrong" approach by other child and adolescent psychiatrists.
7. Your clinical judgment is the determining factor.

GENERAL THOUGHTS

Protect minor patient's confidentiality, unless:

- Mandated report
- Safety of patient
- Safety of third party
- Valid legal compulsion
  - Authorization
  - Court order

WOULD YOU TELL HER PARENTS?

Riley, a 16 year old 11th grader, shares with you at the beginning of treatment that she's felt "bummed on and off" for 3 years. She says its hard to sleep at night and she has trouble concentrating on schoolwork. She denies suicidal ideation. The only thing that helps her is marijuana – she smokes once or twice nearly every day. She denies using tobacco or other recreational drugs. She admits to drinking alcohol 3 times but didn't like the effect because she felt "too out of control." She denies smoking marijuana while driving or at school.

Goldsmith M and Roberts LW. Ethical Issues in Child and Adolescent Psychiatry. Focus 14(1):64-67 (2016)

COMMUNICATE WITH PARENTS – DUAL ROLES

Custody disputes – Manage parents' expectations.

- Treating vs. forensic
  - Conflicting obligations
    - Child's clinical needs vs. parent's legal needs
  - Avoid opinions
    - Facts only
  - Possible scapegoat

COMMUNICATION – ONGOING ASSESSMENT

Suicide Risk Assessment

- Formal assessment tool is recommended
  - Ex: SAFE-T
- Document assessment
- Assess and document after initial assessment
- Do not rely solely on “no harm contracts”

Youth Voice Tip Sheet

Communication Between Child and Adolescent Psychiatrist & Youth

10 Tips to Improve the Conversation

January 2012

AMERICAN ACADEMY OF CHILD & ADOLESCENT PSYCHIATRY
WWW.AACAP.ORG

This Tip Sheet was developed to provide guidance for how child and adolescent psychiatrists can more effectively communicate and partner with young people.

1. **Learn how to talk to us, and get to know us**:
   - Learn our names, and talk to us with interest and respect.
   - Show us genuine concern, so we know that what we say really matters to you.
   - Learn about our lives, and have a conversation with us as people.
   - Look at us and not just our file, when you talk to us.
   - Use words we understand, not jargon.
   - Ask us questions, to help us become active during our meetings.
   - Remember that we notice your tone and your reactions to us, not just what you say.

2. **Be youth-friendly, and learn about youth culture and other aspects of our culture:**
   - Put things in your office like games and magazines to help us feel comfortable.
   - Ask us about our interests, and show us you know something about what we like to do.
   - Ask us how we would like to communicate with you.
   - Learn about Facebook and other social media, and consider creating your own website.
   - Learn about our religion, ethnicity, race, gender, and other parts of our culture.

3. **Listen to us, because we typically don't feel heard:**
   - Understand that it takes time for us to trust, and we may not say too much at first.
   - Be patient with us, and try to understand where we are coming from.
   - Remember that we know what's going on in our lives better than anybody else, and we know ourselves best.
   - Take what we say seriously, even if you don't agree.
   - If you don't understand something we say, ask us to explain.
   - Recognize that we won't always say what you want to hear.
   - Don't be judgmental, because this will shut us down.
   - Try not to make us feel rushed – spend time with us.

https://www.aacap.org/App_Themes/AACAP/docs/youth_resources/misc/Youth_Voice_Tip_Sheet_2012.pdf

COMMUNICATE WITH OTHER PROVIDERS - TREATMENT DELIVERY ARRANGEMENTS

- **Collaboration:** mutually shared responsibility for patient's care in accordance with the qualifications and limitations of each professional's discipline and abilities.
- **Split Treatment:** one psychiatrist (or physician) provides medication management and another psychiatrist provides psychotherapy
  - May be interpreted as supervision if therapist is non-physician provider.
  - No change in psychiatrist's duty to the patient – always liable for ensuring that patient receives appropriate care.

COMMUNICATE WITH OTHER PROVIDERS - TREATMENT DELIVERY ARRANGEMENTS

Ex. Split Treatment – Risk Management Advice:

- Communication among all parties
  - Patient MUST allow
- Split treatment agreement to clarify relationship
- Clarify division of treatment responsibilities and that neither provider supervises the other, if that is the case
  - Example: who will patient contact for what?

COMMUNICATE WITH OTHER PROVIDERS – CONSULTATION

Give and get consults:

- Never hesitate to obtain a consult with a more experienced C&A psychiatrist.
- If you are an experienced C&A psychiatrist, please give consults when asked.
- Consults are low-risk and will be key in addressing shortage of C&A psychiatrists!

RISK MANAGEMENT STRATEGY #3: CAREFULLY DOCUMENT

CAREFULLY DOCUMENT

Thought process:

- Treatment options/actions considered
- Options/actions were chosen and why
- Options/actions were rejected and why

CAREFULLY DOCUMENT

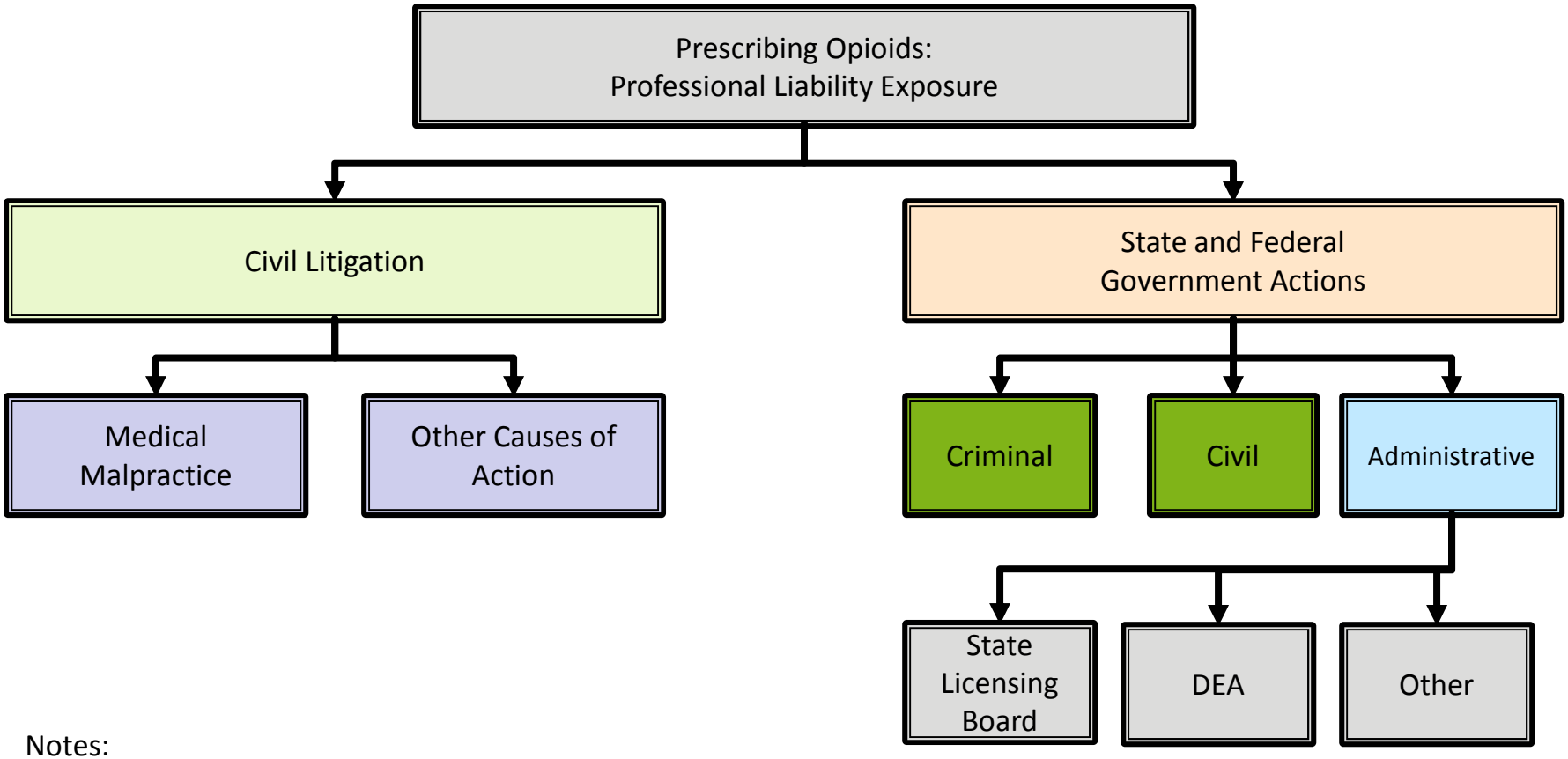
Critical junctures for documentation:

- First psychiatric assessment or admission
- Informed consent process
- Significant clinical changes
  - Such as occurrence of suicidal behavior or ideation
- Monitoring

ADDICTION PSYCHIATRY

WHAT WE'LL COVER

- Liability overview
  - Prescribing opioids in general
  - Specifically prescribing buprenorphine
- Buprenorphine
  - What's required to start
  - How to do it
- 42 CFR Part 2



Notes:

* These actions are <u>not</u> mutually exclusive
* Professional liability insurance policies do not cover all of theses actions

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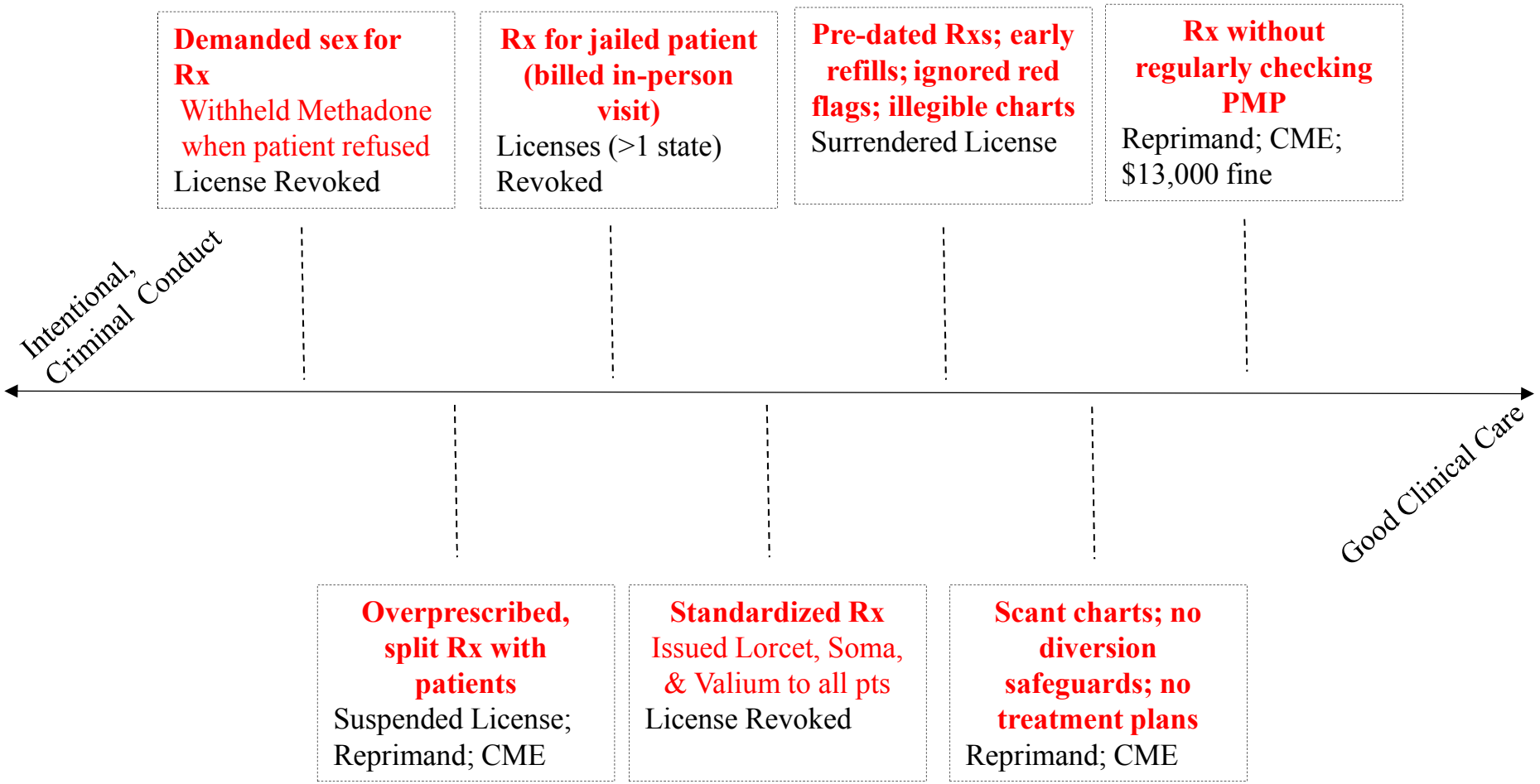

Demanded sex for Rx
Withheld Methadone when patient refused
License Revoked
Rx for jailed patient (billed in-person visit)
Licenses (>1 state) Revoked
Pre-dated Rxs; early refills; ignored red flags; illegible charts
Surrendered License
Rx without regularly checking PMP
Reprimand; CME; $13,000 fine
Intentional,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

Medication-Assisted Treatment

Medication and Counseling Treatment

Training Materials and Resources

Buprenorphine Waiver Management

Practitioner and Program Data

Qualify for NP and PA Waivers

Publications and Research

State Grant Programs

Buprenorphine Practitioner Verification for Pharmacists

Buprenorphine Training for Physicians

Buprenorphine Training for Physicians

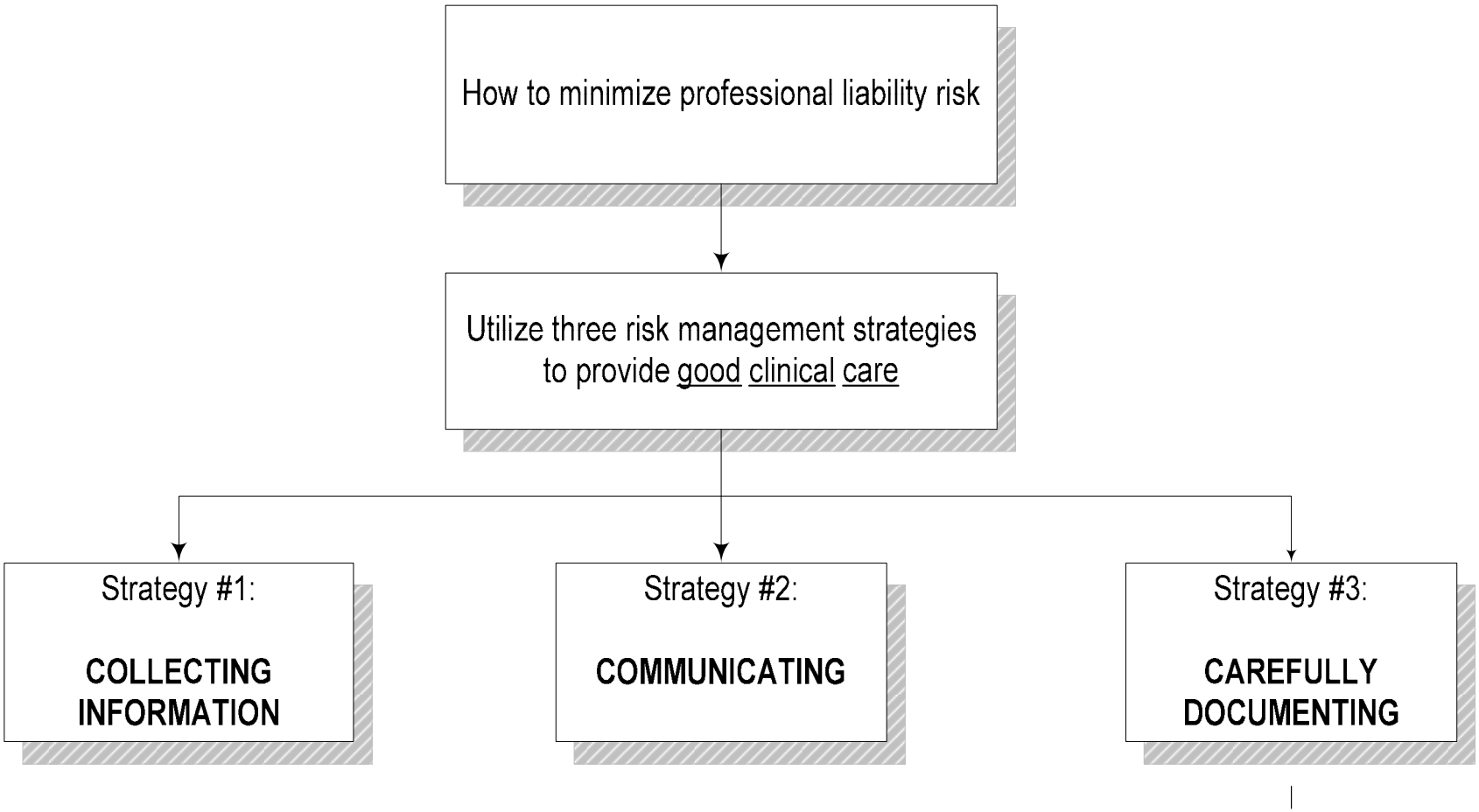
Find information about the eight-hour buprenorphine waiver training courses that are required for physicians to prescribe and dispense buprenorphine.

Under the Drug Addiction Treatment Act of 2000 (DATA 2000), physicians are required to complete an eight-hour training to qualify for a waiver to prescribe and dispense buprenorphine. The following SAMHSA-supported continuing medical education (CME) courses can help physicians qualify to prescribe buprenorphine in an office setting (courses may require registration and include fees):

- The Buprenorphine Waiver Training at the American Academy of Addiction Psychiatry covers legislation, pharmacology, safety, patient assessment, and more. Complete all the modules and pass the post-test at the end

Related SAMHSA Resources

» Behavioral Health Treatments and



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COLLECT INFORMATION

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

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).

Approved Risk Evaluation and Mitigation Strategies (REMS)

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Suboxone/Subutex *(buprenorphine and naloxone/buprenorphine)*

NDA #020733 NDA #022410 NDA #020732

REMS last update: 10/26/2018

- View the Suboxone/Subutex Prescribing Information at DailyMed
- View Suboxone/Subutex's Regulatory Information at Drugs@FDA
- View the Suboxone/Subutex Prescribing Information and Medication Guide at DailyMed
- View Suboxone/Subutex's Regulatory Information at Drugs@FDA
- View Suboxone/Subutex's Regulatory Information at Drugs@FDA

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

This REMS does not apply to SUBOXONE sublingual film, Authorized Generic of SUBOXONE sublingual film, SUBOXONE sublingual tablets, and SUBUTEX sublingual tablets dispensed to patients admitted to an Opioid Treatment Program (OTP) under 42 CFR Part 8 because the care of OTP patients is subject to specific requirements under those regulations.

I. GOAL(S):

The goals of the REMS for SUBOXONE sublingual film, Authorized Generic of SUBOXONE sublingual film, SUBOXONE sublingual tablets, and SUBUTEX sublingual tablets are to:

- Mitigate the risks of accidental overdose, misuse and abuse
- Inform prescribers, pharmacists, and patients of the serious risks associated with SUBOXONE sublingual film, Authorized Generic of SUBOXONE sublingual film, SUBOXONE sublingual tablets, and SUBUTEX sublingual tablets

II. REMS ELEMENTS:

A. Medication Guide

A Medication Guide will be dispensed with each SUBOXONE sublingual film, Authorized Generic of SUBOXONE sublingual film, SUBOXONE sublingual tablets, and SUBUTEX sublingual tablets prescription in accordance with 21 CFR 208.24.
The Medication Guides for buprenorphine-containing products are part of the SUBOXONE sublingual film, Authorized Generic of SUBOXONE sublingual film, SUBOXONE sublingual tablets, and SUBUTEX sublingual tablets REMS and will be provided with the product and is also available by going online to www.suboxoneREMS.com or calling 1-866-463-4846.

B. Elements to Assure Safe Use

1. Safe use conditions

a. SUBOXONE sublingual film, Authorized Generic of SUBOXONE sublingual film, SUBOXONE sublingual tablets, and SUBUTEX sublingual tablets will only be dispensed by the prescriber or prescribed to patients with documentation of

the following safe use conditions:

i. Verification that the patient meets the diagnostic criteria for opioid dependence.
ii. Risks described in the professional labeling and the Medication Guide have been discussed with the patient.
iii. Safe storage of the medication has been explained and reviewed with the patient.
iv. After appropriate induction, the patient is prescribed a limited amount of medication at the first visit.

b. Prescribers will document safe use conditions for each patient by using the 'Appropriate Use Checklist,' or by using another method (e.g. electronic health record) specific to the prescriber's office practice.
c. Indivior Inc. will ensure that within 30 days of FDA approval of the SUBOXONE sublingual film, Authorized Generic of SUBOXONE sublingual film, SUBOXONE sublingual tablets, and SUBUTEX sublingual tablets REMS, a Dear Prescriber Letter will be mailed to all providers certified to treat opioid dependence under the Drug Addiction Treatment Act of 2000 (DATA 2000). This letter is designed to convey and reinforce the risks of accidental overdose, misuse, and abuse of SUBOXONE sublingual film, Authorized Generic of SUBOXONE sublingual film, SUBOXONE sublingual tablets, and

2. Monitoring

a. Each patient using SUBOXONE film will be subject to the following monitoring:

   i. Return visits are scheduled at intervals commensurate with patient stability. Weekly, or more frequent, visits are recommended for the first month.

   ii. Assessment and reinforcement of patient's compliance with the prescribed medication.

   iii. Assessment of appropriateness of dosage prescribed.

   iv. Assessment of whether patient is receiving the necessary psychosocial support.

   v. Assessment of whether patient is making adequate progress towards treatment goals.

INDIVIOR™

APPROPRIATE USE CHECKLIST:

SUBOXONE® SUBLINGUAL FILM, AUTHORIZED GENERIC OF SUBOXONE® SUBLINGUAL FILM, SUBOXONE® SUBLINGUAL TABLET, AND SUBUTEX® SUBLINGUAL TABLET

This checklist is a useful reminder of the safe use conditions and monitoring requirements for prescribing SUBOXONE (buprenorphine and naloxone) Sublingual Film CIII, Authorized Generic of SUBOXONE (buprenorphine and naloxone) Sublingual Film CIII, SUBOXONE (buprenorphine and naloxone) sublingual tablets CIII, or SUBUTEX (buprenorphine) sublingual tablets CIII for opioid dependence.

Requirements to address during each patient's appointment include:

- understanding and reinforcement of safe use conditions
- the importance of psychosocial counseling
- screening and monitoring patients to determine progress towards treatment goals

If a patient continues to abuse various drugs or is unresponsive to treatment, including psychosocial intervention, it is important that you assess the need to refer the patient to a specialist and/or a more intensive behavioral treatment environment.

Additional resource: Providers Clinical Support System: www.pcssnow.org

INDIVIOR™

APPROPRIATE USE CHECKLIST:

SUBOXONE® SUBLINGUAL FILM, AUTHORIZED GENERIC OF SUBOXONE® SUBLINGUAL FILM, SUBOXONE® SUBLINGUAL TABLET, AND SUBUTEX® SUBLINGUAL TABLET

This checklist may be used for visits following the induction period and filed in patient's medical record to document safe use conditions.

Measurement to Ensure Appropriate Use	NOTES:
Date: **Visit #:**	
Maintenance	
◯ Assessed and encouraged patient to take medication as prescribed > Consider pill/film count/dose reconciliation	

COLLECT INFORMATION – ABOUT THE MEDICATIONS

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

Drug Safety and Availability
Drug Alerts and Statements
Medication Guides
Drug Safety Communications
Drug Shortages
Postmarket Drug Safety Information for Patients and Providers
Information by Drug Class
Medication Errors
Drug Safety Podcasts
Safe Use Initiative
Drug Recalls

FDA Drug Safety Communication: FDA warns about serious risks and death when combining opioid pain or cough medicines with benzodiazepines; requires its strongest warning

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

The FDA has issued new information about the combined use of medication-assisted treatment (MAT) drugs with benzodiazepines or other central nervous system depressants. See the **FDA Drug Safety Communication** issued on 9-20-2017.

Safety Announcement

[8-31-2016] A U.S. Food and Drug Administration (FDA) review has found that the growing combined use of opioid medicines with benzodiazepines or other drugs that depress the central nervous system (CNS) has resulted in serious side effects, including slowed or difficult breathing and deaths. Opioids are used to treat pain and cough; benzodiazepines are used to treat anxiety, insomnia, and seizures. In an effort to decrease the use of opioids and benzodiazepines, or opioids and other CNS depressants, together, we are adding

Drug Safety and Availability
Drug Alerts and Statements
Medication Guides
Drug Safety Communications
Drug Shortages
Postmarket Drug Safety Information for Patients and Providers
Information by Drug Class
Medication Errors
Drug Safety Podcasts
Safe Use Initiative
Drug Recalls

FDA Drug Safety Communication: FDA urges caution about withholding opioid addiction medications from patients taking benzodiazepines or CNS depressants: careful medication management can reduce risks

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

This provides updated information to the **FDA Drug Safety Communication: FDA warns about serious risks and death when combining opioid pain or cough medicines with benzodiazepines; requires its strongest warning** issued on August 31, 2016.

Safety Announcement

[9-20-2017] Based on our additional review, the U.S. Food and Drug Administration (FDA) is advising that the opioid addiction medications buprenorphine and methadone should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS). The combined use of these

COLLECT INFORMATION – ABOUT TREATMENT / STANDARD OF CARE

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

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.

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.

CA BUSINESS & OCCUPATIONS 2239

"(a) The use or prescribing for or administering to himself or herself of any controlled substance…constitutes unprofessional conduct…"

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"

VA-DoD

- Screening
- Treatment (medications & psychosocial interventions)
- Promoting group mutual health (AA, NA)
- Address co-occurring mental health conditions and psychosocial problems
- Continuing care guided by ongoing assessment
- Stabilization and recovery

SUD	Medications	Psychosocial Intervention
Alcohol	Acamprosate Disulfiram Naltrexone Topiramate Gabapentin	Behavioral Couples Therapy Cognitive Behavioral Therapy (CBT) Community Reinforcement Approach (CRA) Motivation Enhancement Therapy (MET)
Opioid	Buprenorphine Methadone ER-Injectable Naltrexone	Medical Management Contingency Management (CM)/Individual Drug Counselling (IDC)
Cannabis		CBT/MET
Stimulant		CBT/CRA/IDC CM (?)

www.healthquality.va.gov/guidelines/mh/sud/

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

Practitioner's Manual

An Informational Outline of the Controlled Substances Act

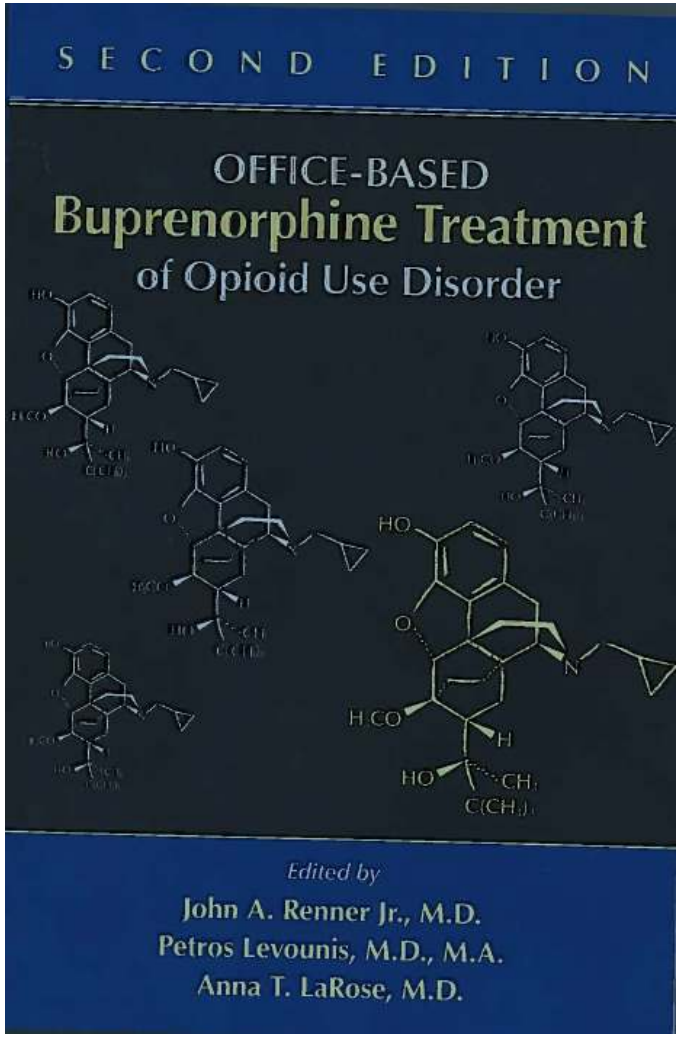
http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf

Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction

A Treatment Improvement Protocol

TIP 40

http://buprenorphine.samhsa.gov/Bup_Guidelines.pdf


SECOND EDITION
OFFICE-BASED
Buprenorphine Treatment
of Opioid Use Disorder
Edited by
John A. Renner Jr., M.D.
Petros Levounis, M.D., M.A.
Anna T. LaRose, M.D.

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.

FSMB: MODEL POLICY ON DATA 2000 AND TREATMENT OF OPIOID ADDICTION IN THE MEDICAL OFFICE

SECTION II: GUIDELINES

- Physician Qualifications
- Patient Assessments
- Treatment Planning
- Educating the Patient
- Informed Consent
- Treatment Agreement
- Induction, Stabilization, and Follow-up
- Adjusting the Treatment Plan
- Preventing and Managing Relapse
- Duration of Treatment
- Medical Records

www.fsmb.org/pdf/2013_model_policy_treatment_opioid_addiction.pdf

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

SECTION II: GUIDELINES

- Understanding Pain
- Patient Evaluation and Risk Stratification
- Development of a Treatment Plan and Goals
- Informed Consent and Treatment Agreement
- Initiating an Opioid Trial
- Ongoing Monitoring and Adapting the Treatment Plan
- Periodic Drug Testing
- Consultation and Referral
- Discontinuing Opioid Therapy
- Medical Records
- Compliance with Controlled Substance Laws and Regulations

www.fsmb.org/pdf/pain_policy_july2013.pdf

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

UNIVERAL PRECAUTIONS – SUMMARIZED:

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

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

UNIVERSAL PRECAUTIONS – CONTINUED

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

SPECIAL REQUIREMENTS FOR PRESCRIBING CONTROLLED SUBSTANCES VIA TELEPSYCHIATRY

- State law – may or may not allow
- Federal law –
  - DEA registration required in patient's state
    - And in state where prescriber is, if different
  - "One in-person visit" rule

FEDERAL REGULATION OF PRESCRIBING CONTROLLED SUBSTANCES

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

U.S. DEPARTMENT OF JUSTICE ★ DRUG ENFORCEMENT ADMINISTRATION

DIVERSION CONTROL DIVISION

Use of Telemedicine While Providing Medication Assisted Treatment (MAT)

Under the Ryan Haight Act of 2008, where controlled substances are prescribed by means of the Internet, the general requirement is that the prescribing Practitioner must have conducted at least one in-person medical evaluation of the patient. U.S.C. § 829(e). However, the Act provides an exception to this requirement. 21 USC § 829 (e)(3)(A). Specifically, a DEA-registered Practitioner acting within the United States is **exempt** from the requirement of an in-person medical evaluation as a prerequisite to prescribing or otherwise dispensing controlled substances by means of the Internet **if** the Practitioner is engaged in the practice of telemedicine and is acting in accordance with the requirements of 21 U.S.C. § 802(54).

Under 21 U.S.C. § 802(54)(A),(B), for **most** (DEA-registered) Practitioners in the United States, **including** Qualifying Practitioners and Qualifying Other Practitioners ("Medication Assisted Treatment Providers"), who are using FDA approved Schedule III-V controlled substances to treat opioid addiction, the term "practice of telemedicine" means the practice of medicine in accordance with applicable Federal and State laws, by a practitioner (other than a pharmacist) who is at a location remote from the patient, and is communicating with the patient, or health

www.hhs.gov/opioids/sites/default/files/2018-09/hhs-telemedicine-dea-final-508compliant.pdf

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H.R.6 - SUPPORT for Patients and Communities Act

115th Congress (2017-2018) | Get alerts

BILL Hide Overview

Sponsor: Rep. Walden, Greg [R-OR-2] (Introduced 06/13/2018)

Committees: House - Energy and Commerce; Ways and Means; Judiciary

Latest Action: Senate - 10/04/2018 Message on Senate action sent to the House. (All Actions)

Roll Call Votes: There have been 4 roll call votes

Tracker:

Introduced | Passed House | Passed Senate | **Resolving Differences** | To President | Became Law

More on This Bill

Constitutional Authority Statement

CBO Cost Estimates [2]

Subject — Policy Area:

Health

View subjects »

Summary (1) | Text (6) | Actions (54) | Related Bills (99)

https://www.congress.gov/bill/115th-congress/house-bill/6

COLLECT INFORMATION – ABOUT ABUSE

Review in envelope:

- DEA problem areas
- MO's
- DEA suggestions

COLLECT INFORMATION - ENFORCEMENT

DEA VISITS

- CSA authorizes DEA to enter controlled premises and conduct periodic inspections
- Buprenorphine prescribers:
  - "Inspection" – investigators look at records for buprenorphine patients
    - Need log of buprenorphine patients and prescriptions in location listed on DEA registration
  - "Audit" – if also dispenses, will look at meds received and dispensed

PCSS-B Training
An Educational Resource for Those Treating Patients with Opioid Use Disorders

How to Prepare for a Visit from the Drug Enforcement Agency (DEA) Regarding Buprenorphine Prescribing

The following document was prepared by the partner organizations of the Physicians' Clinical Support System-Buprenorphine. It provides background information regarding DEA inspection procedures and suggestions on how buprenorphine waivered physicians can prepare for a DEA inspection of their office-based practice.

1. Regulations

Congress passed the Drug Addiction Treatment Act (DATA) on October 17, 2000. This act permits qualified physicians to administer or dispense Schedule III, IV, or V narcotic medications, that have been approved for the maintenance and detoxification treatment of a narcotic dependent person. Thus far, the Food and Drug Administration has only approved the use of buprenorphine (mono formulation) and buprenorphine/naloxone for this purpose. The DEA is authorized by the Controlled Substances Act (21 U.S.C. 822 (f) 880 and 21 CFR 1316.03 to enter controlled premises (registered locations) and conduct periodic inspections to ensure compliance with recordkeeping, security and other requirements of the Controlled Substances Act.

2. DEA Inspections of DATA-Waived Physicians

The Drug Enforcement Administration (DEA) is responsible for ensuring that physicians who are registered with DEA pursuant to the Drug Addiction Treatment Act of 2000 (DATA 2000) comply with recordkeeping, security, and other requirements for administering, dispensing or

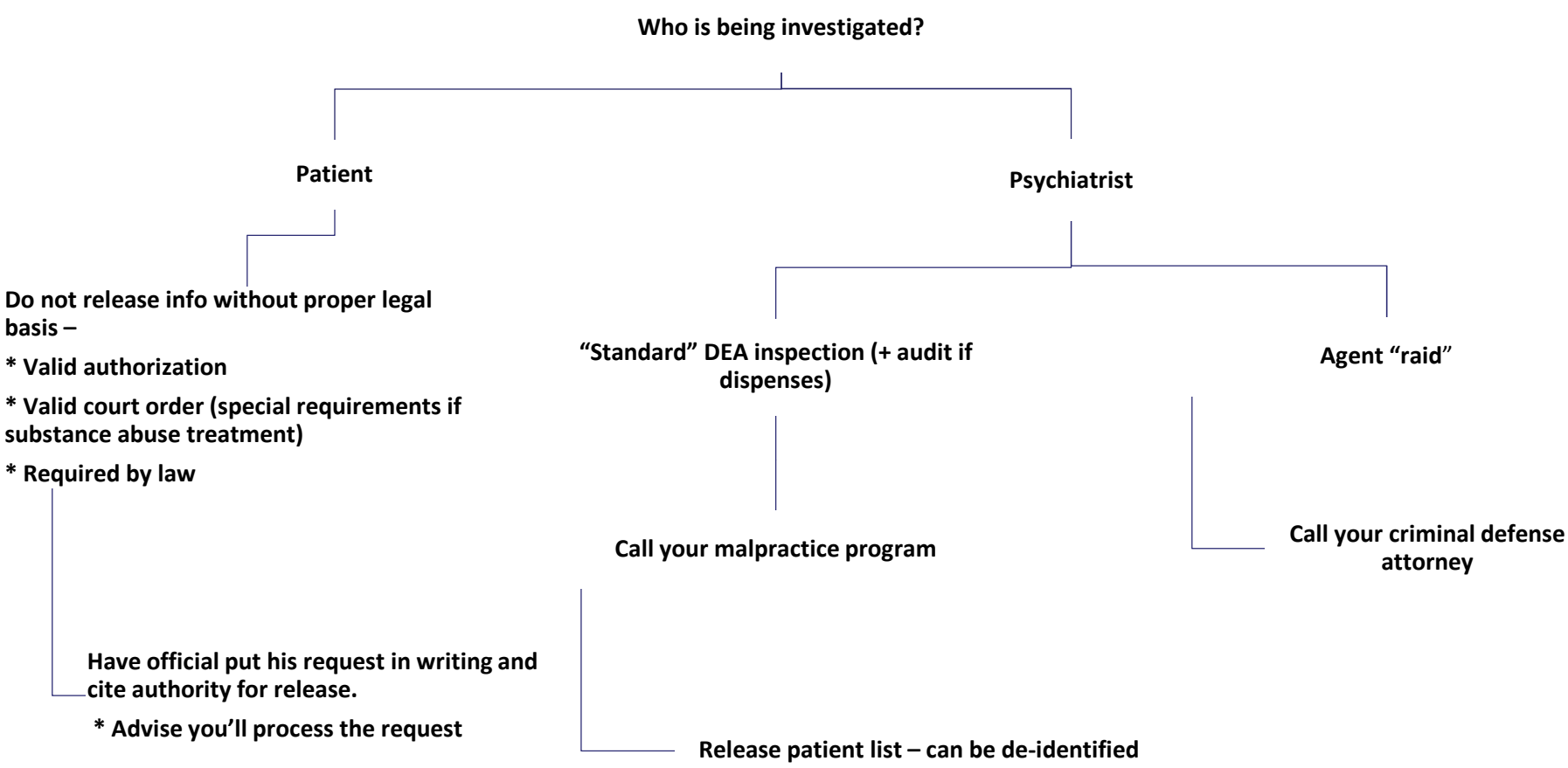
www.aaap.org/content/how-prepare-visit-drug-enforcement-administration-dea-regarding-buprenorphine-prescribing

COLLECT INFORMATION – CRIMINAL ENFORCEMENT

- Focus of government
  - Prescribing in large quantities
  - Prescribing without checking PMP
  - Prescribing for patients who fatally overdose
  - Inappropriate prescribing to Medicare beneficiaries
  - Etc.

- Plan ahead!
  - May need criminal defense attorney on speed dial

Government Official Comes to Your Office Wanting Patient Information



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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

MEDICATION GUIDE

Buprenorphine (byoo-pre-NOR-feen) and Naloxone (nal-OX-own)

Sublingual Film for sublingual or buccal administration (CIII)

IMPORTANT:

Keep buprenorphine and naloxone sublingual film in a secure place away from children. Accidental use by a child is a medical emergency and can result in death. If a child accidentally uses buprenorphine and naloxone sublingual film, get emergency help right away.

Read this Medication Guide that comes with buprenorphine and naloxone sublingual film before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor. Talk to your doctor or pharmacist if you have questions about buprenorphine and naloxone sublingual film.

Share the important information in this Medication Guide with members of your household.

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

What should I avoid while taking buprenorphine and naloxone sublingual film?

- **Do not drive, operate heavy machinery, or perform any other dangerous activities until you know how this medication affects you**. Buprenorphine can cause drowsiness and slow reaction times. This may happen more often in the first few weeks of treatment when your dose is being changed, but can also happen if you drink alcohol or take other sedative drugs when you take buprenorphine and naloxone sublingual film.
- **You should not drink alcohol while using buprenorphine and naloxone sublingual film**, as this can lead to loss of consciousness or even death.

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 – 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

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 Opioids

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

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42 CFR PART 2
CONFIDENTIALITY OF SUBSTANCE USE DISORDER PATIENT RECORDS:
WHAT PSYCHIATRISTS NEED TO KNOW

WHAT IS A "PROGRAM"?

A "Program" covered by Part 2 is one that offers substance abuse education, treatment or prevention and is regulated or assisted by the federal government.

Defining a Part 2 Program is a fact-specific determination.

WHAT IS A "PROGRAM"?

First, a "Program" means:

- An **individual** or **entity** (other than a general medical facility) who **holds itself out** as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or
  - *The phrase "**holds itself out**" is not defined in the regulations, but can be understood to mean several things, such as advertising or posting notices in the office, certifications in addiction medicine, internet statements, or any activity that would lead one to reasonably conclude that the provider is providing or provides alcohol or drug abuse diagnosis, treatment, or referral treatment.*
- An identified **unit** within a general **medical facility** that **holds itself** out as providing, and provides, substance use disorder diagnosis, treatment, or referral for treatment; or
- **Medical personnel** or other staff in a general medical facility whose **primary function** is the provision of substance use disorder diagnosis, treatment, or referral for treatment and who are identified as such providers.

WHAT IS A "PROGRAM"?

AND….second, the Program must also be "federally assisted," which is broadly defined as meaning the Program is:

- being operated by a department or agency of the United States;
- operating based on the authorization on of a department or agency of the United States (e.g., the Program has received a license, certification, registration, or other authorization from the government);
- receiving federal financial assistance or is part of an organization receiving federal financial assistance; or
- receives tax deductions or is operating under tax-exempt status.

WHAT IS A "QSO"?

A Qualified Service Organization (QSO) is defined as an individual or entity who:

(1) Provides services to a Part 2 Program, such as data processing, bill collecting, dosage preparation, laboratory analyses, or legal, accounting, population health management, medical staffing, or other professional services, or services to prevent or treat child abuse or neglect, including training on nutrition and child care and individual and group therapy [*think Business Associate under HIPAA*], and

(2) Has entered into a written agreement with a Part 2 Program under which that individual or entity:

(i) Acknowledges that in receiving, storing, processing, or otherwise dealing with any patient records from the Part 2 Program, it is fully bound by the regulations in this part [*think Business Associate Agreement under HIPAA*]; and

(ii) If necessary, will resist in judicial proceedings any efforts to obtain access to patient identifying information related to substance use disorder diagnosis, treatment, or referral for treatment except as permitted by the regulations in this part [*no similar requirement under HIPAA*].

HIPAA VS. PART 2

	HIPAA Regulations	Part 2 Regulations
Agreements with third parties to whom information is disclosed for the third party to provide a service	Business Associate Agreement (BAA)	Qualified Service Organization Agreement (QSOA) Note: The limited provisions required by Part 2 can be incorporated into a BAA
Notice to patient	Notice of Privacy Policies (NPP)	Notice to Patients of Federal Confidentiality Requirements Note: The limited provisions required by Part 2 can be incorporated into the NPP
Patient permission to release information **(See Appendix IV for the required elements under both regulations)**	Authorization	Consent Note: The requirements are very similar; provisions required by Part 2, if not already in the authorization, can be added to the authorization. Example: New York Courts authorization form (http://www.nycourts.gov/forms/Hipaa_fillable.pdf) covers HIPAA and Part 2, as well as state law.

WHAT DO THE REGULATIONS SAY?

- Patients must be provided with a notice of their rights at the outset of treatment
- Only limited disclosures of patient information are allowed
- All disclosed records must have a statement on them prohibiting further re-disclosure
  - 2 options:
    - Long
    - Short: "42 CFR Part 2 prohibits unauthorized disclosure of these records"
- Patients may request a list of entities to whom their information has been disclosed
- There are criminal penalties for violation
- Enforcement is by the local US Attorney's office; if the Program that allegedly violated Part 2 is an opioid treatment Program, violations can also be reported to the SAMSHA office responsible for opioid treatment Program oversight
- Etc.

ONLY LIMITED DISCLOSURES ALLOWED

- With patient's written consent that complies with Part 2's requirements
  - Disclosing only that information necessary to carry out the stated purpose of the disclosure.
- To a QSO pursuant to a written QSOA
  - Disclosing only that information necessary for the QSO to perform its duties under the QSOA.
- In medical emergencies
- For research
- For audit and evaluation purposes
- With a court order that complies with Part 2's requirements
  - Regular court orders will not suffice
  - SUBPOENA IS NOT SUFFICIENT

CHECKLIST FOR PART 2 PROGRAMS UNDER 42 CFR PART 2

- ☐ Train staff and employees to understand and comply with regulations.

  NOTE: *Part 2 training can be incorporated into your HIPAA training – initial training upon hiring and annual training.*

- ☐ Consider having staff sign confidentiality agreements.

- ☐ Inform patients about confidentiality by 1) informing patients that federal law and regulations protect their patient records and 2) giving patients a written summary of federal law and regulations. § 2.22

  NOTE: *This Part 2 patient notice can be incorporated into a HIPAA Notice of Privacy Practices.*

- ☐ Part 2 programs must have in place formal policies and procedures to protect unauthorized uses and disclosures of patient identifying information and protect against security threats to patient identifying information. § 2.16

- ☐ Must not re-disclose patient records without patient consent, unless a limited exception applies. § 2.32

- ☐ Ensure consent form for release of Part 2 records complies with Part 2 requirements. § 2.31

- ☐ When a disclosure is made in connection with a medical emergency, the Part 2 Program must document the name of the recipient of information, the date and time of disclosure.

and nature of the emergency. § 2.51

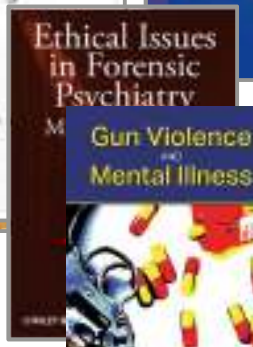
- ☐ Must not release patient records per subpoena. § 2.61
- ☐ Must not release patient records per regular court order. § 2.61
- ☐ Have a Qualified Service Organizations Agreement prior to disclosing Part 2 information to a Qualified Service Organization. § 2.11

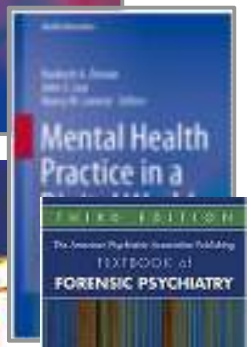
  NOTE: *This Part 2 agreement can be incorporated into your HIPAA Business Associate Agreement.*

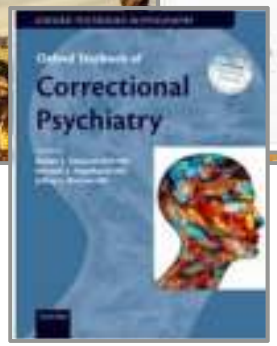
- ☐ The amount of information disclosed to a qualified service organization must be limited to that information which is necessary to carry out the purpose of the disclosure. § 2.13
- ☐ Upon request, must provide patients who have consented to disclose their patient identifying information a list of entities to which their information has been disclosed to § 2.13
- ☐ If a Part 2 Program is discontinued or is acquired by another program it must remove patient identifying information from its records or destroy its records unless patient gives consent to transfer the records or there is a legal requirement to keep the records for a certain period. § 2.19

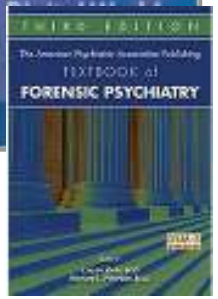
MEDICAL MARIJUANA

DONNA VANDERPOOL, MBA, JD









State Approaches to Marijuana

(Non-exclusive)

Decriminalization

Medical

Recreational

TERMINOLOGY

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

FEDERAL LAW

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

FEDERAL LAW

Exceptions

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

FEDERAL LAW

Consequences of marijuana being Schedule I/illegal

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

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

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

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

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

www.atf.gov/firearms/docs/4473-part-1-firearms-transaction-record-over-counter-atf-form-53009/download

FEDERAL LAW

Consequences of marijuana being Schedule I/illegal

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

Linked in Sign in Join now

Feds Ban Gun Sales to Marijuana Users - Part 2

Donna Vanderpool, MBA, JD | Follow
VP, Risk Management at PRMS...

7 0 0

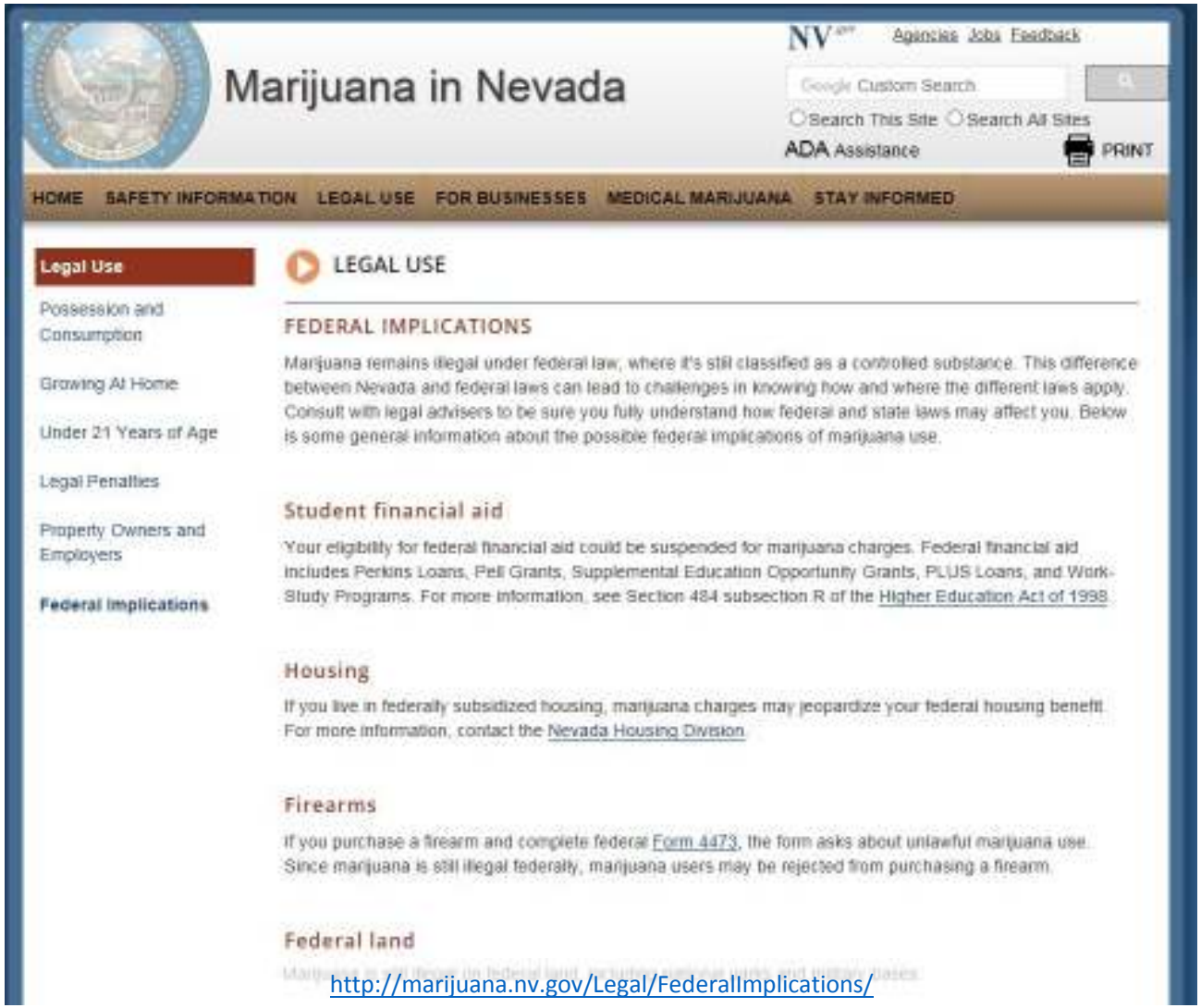
In my last post, Part 1, I covered the Department of Justice's position that federal law prohibits any person who is an unlawful user of or addicted to any controlled substance from possessing firearms. Marijuana is a schedule 1 controlled substance, so its use is unlawful under federal law. This is true even if state law has legalized or decriminalized marijuana for medicinal or recreational purposes.

Do you think that this amounts to violations of Constitutional rights? A Nevada woman believes so, but not the judiciary disagreed. Here's the case: the woman had sought and obtained a medical marijuana card from the state registry. When she tried to buy a firearm, the seller knew she had a registry card, and per the DOJ's letter (detailed in Part 1), refused to sell her a firearm because of her marijuana card. She sued the federal government alleging the following:

FEDERAL LAW

Consequences of marijuana being Schedule I/illegal

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



http://marijuana.nv.gov/Legal/FederalImplications/

FEDERAL ENFORCEMENT IN STATES ALLOWING MARIJUANA

DOJ enforcement memos

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

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

January 4, 2018

MEMORANDUM FOR ALL UNITED STATES ATTORNEYS

FROM: Jefferson B. Sessions, III
Attorney General

SUBJECT: Marijuana Enforcement

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

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

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

FEDERAL ENFORCEMENT IN STATES ALLOWING MARIJUANA

2014 Congressional Budget Amendment

- Prohibiting DOJ from using funds to prevent states from implementing their medical marijuana laws
- Rohrabacher Amendment
  - Renewed by President 2-15-19
    - Until 9-30-19

FEDERAL ENFORCEMENT - THE KETTLE FALLS FIVE CASE

- 2013: indictment
- 2014: Congressional amendment prohibiting DOJ from using funds to prevent states from implementing their medical marijuana laws
- 2015: prosecution continues
- 2017: feds finally agreed – no $ to prosecute
  - But doesn't drop charges
- January 2018: case dropped, but "with prejudice"
  - Can be brought again
- June 2018: Statute of limitations ran out

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

http://www.ncsl.org/bookstore/state-legislatures-magazine/marijuana-deep-dive.aspx

QUALIFIED PHYSICIANS

WHO MAY RECOMMEND MEDICAL MARIJUANA

- "Attending provider of health care:"
  1. Is licensed or certified to practice a profession which authorizes the person to write a prescription for a medication to treat a chronic or debilitating medical condition; and
  2. Has responsibility for the care and treatment of a person diagnosed with a chronic or debilitating medical condition.

Nev. Rev. Stat. § 453A.030

ISSUANCE OF CERTIFICATION FOR MEDICAL MARIJUANA - PA

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

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

35 P.S. § 10231.403

OKLAHOMA LAW

Title 310, Chapter 681: Medical Marijuana Control Program

310:681-1-4. Definitions

- "Physician" means a doctor of medicine or a doctor of osteopathic medicine who holds a valid, unrestricted and existing license to practice in the State of Oklahoma and meets the definition of "board certified" under rules established by either the Oklahoma Board of Medical Licensure or the Oklahoma Board of Osteopathic Examiners.

OKLAHOMA LAW

310:681-1-9.1. Recommending physician standards

(a) Any Physician, before making a recommendation for medical marijuana or medical marijuana products under these provisions, shall be in "good standing" with their licensing board. Physicians in residency or other graduate medical training do not meet the definition of Physician under this Subchapter and any recommendation for a patient medical marijuana license will not be processed by the Department.

HOW TO BECOME A QUALIFIED PHYSICIAN - FL

- Have an active and unrestricted license as a medical doctor or osteopathic physician in Florida
- Take the 2-hour course and exam
- Re-take the course each time you have to renew your license

QUALIFYING CONDITIONS

APPROVED CONDITIONS FOR MEDICAL MARIJUANA USE

- AIDS
- Cachexia
- Cancer
- Glaucoma
- Post-traumatic stress disorder (PTSD)
- Persistent muscle spasm or seizures
- Severe nausea or pain
- Other conditions are subject to approval

Nev. Rev. Stat. § 453A.050

QUALIFYING MEDICAL CONDITIONS

(a) Cancer

(b) Epilepsy

(c) Glaucoma

(d) Positive status for HIV

(e) AIDS

(f) PTSD

(g) ALS

(h) Crohn's disease

(i) Parkinson's disease

(j) Multiple sclerosis

(k) Medical conditions of the same kind or class as or comparable to those enumerated in paragraphs (a)-(j)

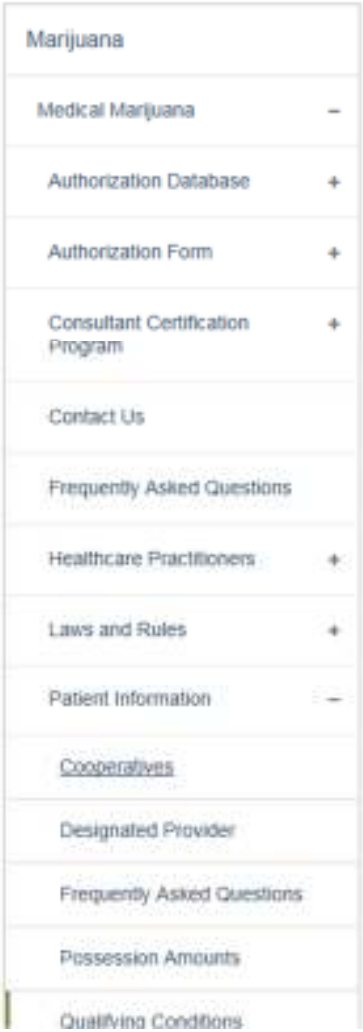
** additional documentation required **

(l) A terminal condition diagnosed by a physician other than the qualified physician issuing the physician certification

(m) Chronic non-malignant pain

(pain caused by qualifying medical condition or that originates from a qualifying medical condition and persists beyond the usual course of that qualifying medical condition)

West's F.S.A. § 381.986



Medical Marijuana

Qualifying Conditions

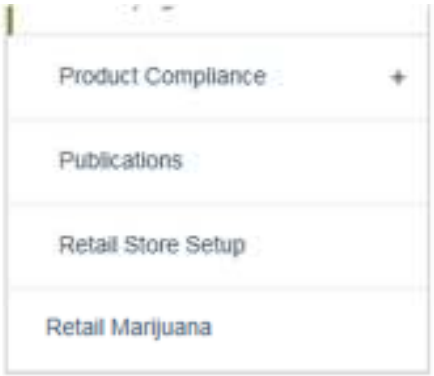
Patients with terminal or debilitating medical conditions may, under their healthcare practitioner's care, benefit from the medical use of marijuana.

Terminal or debilitating medical condition means a condition severe enough to significantly interfere with the patient's activities of daily living and ability to function, which can be objectively assessed and evaluated and limited to the following:

- Cancer, human immunodeficiency virus (HIV), multiple sclerosis, epilepsy or other seizure disorder, or spasticity disorders.
- Intractable pain, limited for the purpose of this chapter to mean pain unrelieved by standard medical treatments and medications.
- Glaucoma, either acute or chronic, limited for the purpose of this chapter to mean increased intraocular pressure unrelieved by standard treatments and medications.
- Crohn's disease with debilitating symptoms unrelieved by standard treatments or medications.
- Hepatitis C with debilitating nausea or intractable pain unrelieved by standard treatments or medications.
- Diseases, including anorexia, which result in nausea, vomiting, wasting, appetite loss, cramping, seizures, muscle spasms, or spasticity, when these symptoms are unrelieved by standard treatments or medications.
- Chronic renal failure requiring hemodialysis.
- Posttraumatic stress disorder.
- Traumatic brain injury.

Humanitarian compassion necessitates that the decision to use marijuana by patients with terminal or debilitating medical conditions is a personal, individual decision, based upon their healthcare practitioner's professional medical judgment and discretion.

https://www.doh.wa.gov/YouandYourFamily/Marijuana/MedicalMarijuana/PatientInformation/QualifyingConditions



Mental health conditions don't qualify

Due to a lack of scientific evidence supporting improved health outcomes from the use of medical marijuana for mental health conditions such as bipolar disorder, depression and anxiety, the Medical Quality Assurance Commission denied requests to add to the list of qualifying conditions. You may read the commission's and board's decision on the latest petition in the final order (PDF).

How to add qualifying conditions

Prior to July 24, 2015, the Medical Quality Assurance Commission, in consultation with the Board of Osteopathic Medicine and Surgery, considered petitions requesting to add conditions for which medical marijuana may be recommended under state law. In 2015, the law changed and petitions are no longer allowed. To add a qualifying condition to the list would require an act of legislation to change the law.

https://www.doh.wa.gov/YouandYourFamily/Marijuana/MedicalMarijuana/PatientInformation/QualifyingConditions

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

ALEX CHANG, Petitioner,	NO. FINAL ORDER ON PETITION FOR INCLUSION OF BIPOLAR DISORDER, SEVERE DEPRESSION AND ANXIETY-RELATED DISORDERS (SOCIAL PHOBIA) AS TERMINAL OR DEBILITATING CONDITIONS UNDER RCW 69.51A.010(4)

This matter came before the Medical Quality Assurance Commission on January 15, 2010 at the Holiday Inn Seattle Renton, Washington, on the petition of Alex Chang, for the inclusion of bipolar disorder, severe depression, and anxiety-related disorders, specifically social phobia as terminal or debilitating medical conditions under RCW 69.51A. The Commission, in consultation with the Board of Osteopathic Medicine and Surgery, having considered the petition and the record in this matter, now issues the following:

I. FINDINGS OF FACT

1.1 On July 20, 2009, the Petitioner Alex Chang filed a petition with the Medical Quality Assurance Commission (Medical Commission) requesting that, pursuant to RCW 69.[illegible] https://www.doh.wa.gov/portals/1/Documents/3000/FinalOrder.pdf [illegible] anxiety-

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 Document

Resource Document on APA Opposition to the Use of Cannabis for PTSD

Approved by the Joint Reference Committee, February 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 Council on Addiction Psychiatry

Abstract

The use of cannabis for medical indications has received considerable attention as several states have moved to legalize cannabis for various purposes. A growing number of patients cite post-traumatic stress disorder (PTSD) as the reason for seeking cannabis for medical purposes in states where it is legal.[1] Furthermore, approximately 15% of Veterans who are treated in Department of Veterans Affairs (VA) outpatient PTSD clinics report recent (past 6 months) cannabis use.[2] This position statement was developed through review of the evidence to date and to establish the APA's consensus on the matter.

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"

NEW YORK STATE OF OPPORTUNITY. Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

Medical Marijuana Program – Practitioner Guidance for Post-Traumatic Stress Disorder (PTSD)

Post-traumatic stress disorder has been added as a qualifying condition for the Medical Marijuana Program through legislation signed by Governor Cuomo on November 11, 2017. This document provides guidance to registered practitioners who may issue certifications for this new qualifying condition.

1. Registered practitioners should review the Diagnosis and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) criteria for the diagnosis of post-traumatic stress disorder (PTSD) to ensure an accurate diagnosis of PTSD has been made and is documented in the patient's medical record prior to issuing a certification for medical marijuana for PTSD.

2. Practitioners are strongly encouraged to consult with their patient's behavioral health specialist prior to initiating medical marijuana treatment. If the patient does not have a relationship with a behavioral health specialist, a referral should be encouraged.

3. Pursuant to 10 NYCRR § 1004.2 (a) (11), practitioners must review past treatments, and determine, in the practitioner's professional medical opinion that the patient is likely to receive therapeutic or palliative benefit from medical marijuana for the serious condition, in this case for the treatment of PTSD.

4. Pursuant to 10 NYCRR § 1004.2 (a) (13), practitioners must discuss with patients the risks versus benefits of medical marijuana.

5. Medical marijuana is not recommended for PTSD patients under 18 years of age.

6. Practitioners should make an effort to determine patients' current or prior cannabis use in determining appropriate frequency and level of dosing, which may differ between patients who are experienced cannabis users and cannabis naïve patients.

7. Practitioners should consider an approach to a treatment plan and document the patient's

https://www.health.ny.gov/regulations/medical_marijuana/practitioner/docs/ptsd_guidance.pdf

CERTIFICATION / RECOMMENDATION REQUIREMENTS

PHYSICIAN DUTIES WHEN RECOMMENDING

- Prior to issuing, modifying or renewing a certification, the practitioner **shall** consult the prescription monitoring program registry.
- Must include a statement that in the practitioner's professional opinion and review of past treatments, the patient is likely to receive therapeutic or palliative benefit from marijuana for the qualifying condition
- Must include a statement that the practitioner has explained the potential risks and benefits of the use of medical marijuana
  - Must explain to the patient's parent or legal guardian if the patient is under the age of 18

10 NYCRR 1004.2

NEW JERSEY LAW – MEDICAL BOARD REGS

NJAC 13:35-7A.5: Written instruction requirements; reassessment; records

(c) A physician authorizing the medical use of marijuana shall review, at a minimum of every three months, the course of treatment for the patient's debilitating medical condition, and the patient's progress toward treatment objectives as a result of the use of medical marijuana, including whether the patient is achieving the therapeutic results intended, has developed significant untoward side effects, or is experiencing any physical or psychological problems associated with marijuana use. If the physician determines that the patient is achieving treatment objectives, and is not experiencing untoward side effects or physical or psychological problems associated with marijuana use, the physician may continue the patient's treatment with medical marijuana without alteration.

NEW JERSEY LAW – MEDICAL BOARD REGS

NJAC 13:35-7A.5: Written instruction requirements; reassessment; records

(f) The physician shall keep accurate and complete records that include:

1. The medical history and physical examination of the patient;
2. The diagnosis of the debilitating medical condition, including the patient's symptoms and their severity and the patient's reaction and response to conventional medical therapies, which qualify the patient for the medical use of marijuana;
3. Other evaluations and consultations;
4. Treatment plan objectives;
5. Evidence of informed consent. In obtaining informed consent, the physician shall advise the patient about the lack of scientific consensus for the medical use of marijuana, its sedative properties and the risks for addiction;
6. Treatments and other drugs prescribed or provided;
7. Any agreements with the patient; and
8. Periodic reviews conducted.

PHYSICIAN CERTIFICATION - MARYLAND

Must certify:

Patient has a condition for which the potential benefits of the medical use of marijuana would likely outweigh the health risks for the patient

MD § 13-3301

CERTIFYING MEDICAL MARIJUANA - FL

To issue a physician certification for medical marijuana, the qualified physician must:

1. Conduct a physical examination in person ***(not via telemedicine)*** and a full assessment of the medical history of the patient;
2. Diagnose the patient with at least one qualifying medical condition;
3. Determine that the use of medical marijuana would highly outweigh the potential health risks;
    - If patient is under 18 years old, a second physician must concur with this judgment
4. Determine whether patient is pregnant – only low-THC cannabis shall be recommended to a patient who is pregnant;
5. Review the patient's controlled drug prescription history in the PDMP;

STANDARDS

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

Guidelines

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

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

OKLAHOMA LAW

310:681-1-9.1 REVISION NOTES

- Required a bona fide physician-patient relationship but no longer required a physician to have ongoing responsibility for the care of the individual.
- Removed requirement for annual assessment of medical need for marijuana and related provision. Statutory language grants 2-year license.
- Required a recommending physician to use the accepted standards a reasonable and prudent physician would use when recommending medication but removes the specific standards previously listed.

INFORMED CONSENT

ELEMENTS OF INFORMED CONSENT - FL

- Federal government – Schedule I
- Lack of FDA oversight
- Research and efficacy to treat qualifying conditions
- Potential for addiction
- Potential effect on coordination, motor skills, and cognition
- Potential side effects
- Risks, benefits, and drug interactions
- Patient's de-identified health information may be used for research

Medical Marijuana Consent Form

A qualified physician may not delegate the responsibility of obtaining written informed consent to another person. The qualified patient or the patient's parent or legal guardian if the patient is a minor must initial each section of this consent form to indicate that the physician explained the information and, along with the qualified physician, must sign and date the informed consent form.

a. **The Federal Government's classification of marijuana as a Schedule I controlled substance.**

_____The federal government has classified marijuana as a Schedule I controlled substance. Schedule I substances are defined, in part, as having (1) a high potential for abuse; (2) no currently accepted medical use in treatment in the United States; and (3) a lack of accepted safety for use under medical supervision. Federal law prohibits the manufacture, distribution and possession of marijuana even in states, such as Florida, which have modified their state laws to treat marijuana as a medicine.

_____When in the possession of medical marijuana, the patient or the patient's caregiver must have his or her medical marijuana use registry identification card in his or her possession at all times.

b. **The approval and oversight status of marijuana by the Food and Drug Administration.**

_____Marijuana has not been approved by the Food and Drug Administration for marketing as a drug. Therefore, the "manufacture" of marijuana for medical use is not subject to any federal standards, quality control, or other federal oversight. Marijuana may contain unknown quantities of active ingredients, which may vary in potency, impurities, contaminants, and substances in addition to THC, which is the primary psychoactive chemical component of marijuana.

c. **The potential for addiction.**

_____Some studies suggest that the use of marijuana by individuals may lead to a tolerance to, dependence on, or addiction to marijuana. I understand that if I require increasingly higher doses to achieve the same benefit or if I think that I may be developing a dependency on marijuana, I should contact Dr. _____ (name of qualified physician).

DISCRIMINATION PROHIBITED

DISCRIMINATION PROHIBITED

For the purposes of medical care, including organ transplants, a registered qualifying patient's authorized use of marijuana in accordance with this chapter shall be considered the equivalent of the authorized use of any other medication used at the direction of a physician, and shall not constitute the use of an illicit substance or otherwise disqualify a qualifying patient from needed medical care.

16 Del. C. § 4905A(a)(2)

PROVIDER TRACKING

BOARDS TRACK CERTIFICATIONS

The Board of Medicine and the Board of Osteopathic Medicine shall jointly create a physician certification pattern review panel that shall review all physician certifications submitted to the medical marijuana use registry. The panel shall track and report the number of physician certifications and the qualifying medical conditions, dosage, supply amount, and form of marijuana certified…

West's F.S.A. § 381.986

PROVIDER TRACKING AND EVALUATIONS

1. The Division will register and track each attending provider of health care who advises a patient that the medical use of marijuana may mitigate the symptoms or effects of the patient's medical condition. To the extent possible, the Division will maintain a confidential record of:

   (a) the number of patients whom the physician advised that the medical use of marijuana may mitigate the symptoms or effects of the patients' medical conditions;

   (b) the chronic or debilitating medical conditions of such patients;

   (c) the number of times the physician advised each patient that the medical use of marijuana may mitigate the symptoms or effects of the patient's medical condition;

   (d) the number of different chronic or debilitating medical conditions for which the physician advised each patient that the medical use of marijuana may mitigate the symptoms or effects of the patient's medical condition; and

   (e) how frequently the physician advises each patient that the medical use of marijuana may mitigate the symptoms or effects of the patient's medical condition.

Nev. Admin. Code § 453A.716

PROHIBITIONS

PROHIBITIONS - PA

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

35 P.S. § 10231.403

PROHIBITIONS - PA

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

35 P.S. § 10231.402

FORMS OF MARIJUANA

FORMS OF MARIJUANA

It is unlawful to:

(1) Smoke medical marijuana

(2) Incorporate medical marijuana into edible form (prior to sale)

35 P.S. § 10231.304(b)

APPROVED FORMS OF MEDICAL MARIJUANA - NY

- Solid or semi-solid dosage forms (such as capsules, tablets, and lozenges);
- Metered liquid or oil preparations (for vaporization or oral administration);
- Metered ground plant preparations;
- Topicals and transdermal patches.
- NO SMOKING
- NO EDIBLES

MINORS

TOO RISKY!!

Marijuana Legalization

Revised May 2017

The American Academy of Child and Adolescent Psychiatry (AACAP) advocates for careful consideration of potential immediate and downstream effects of marijuana policy changes on children and adolescents. Marijuana legalization, even if restricted to adults, may be associated with (a) decreased adolescent perception of marijuana's harmful effects, (b) increased marijuana use among parents and caretakers, and (c) increased adolescent access to marijuana, all of which reliably predict increased rates of adolescent marijuana use and associated problems.[1-3] Marijuana use during pregnancy, occurring at increasing rates, raises additional concerns regarding future infant, child, and adolescent development.[4-6]

AACAP is aware that, among hundreds of chemical constituents, marijuana contains select individual compounds that, if safely administered in reliable doses, may potentially convey therapeutic effects for specific conditions in specific populations.[7] Advocacy regarding potential cannabinoid therapeutics, alongside social justice, public policy, and economic concerns, have contributed to marijuana policy changes. Amid these factors, AACAP remains focused on concerns regarding adolescent marijuana use.

Adolescents are especially vulnerable to marijuana's many known adverse effects.[8,9] One in six adolescent marijuana users develops cannabis use disorder, a well characterized syndrome involving tolerance,

GOAL –
GET FAMILIAR WITH MEDICAL MARIJUANA

Specifically:

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

5.1K + 212

NEWS

The National Academies of SCIENCES · ENGINEERING · MEDICINE

Jan. 12, 2017

FOR IMMEDIATE RELEASE

Nearly 100 Conclusions on the Health Effects of Marijuana and Cannabis-Derived Products Presented in New Report; One of the Most Comprehensive Studies of Recent Research on Health Effects of Recreational and Therapeutic Use of Cannabis and Cannabis-Derived Products

WASHINGTON – A new report from the National Academies of Sciences, Engineering, and Medicine offers a rigorous review of scientific research published since 1999 about what is known about the health impacts of cannabis and cannabis-derived products – such as marijuana and active chemical compounds known as cannabinoids – ranging from their therapeutic effects to their risks for causing certain cancers, diseases, mental health disorders, and injuries. The committee that carried out the study and wrote the report considered more than 10,000 scientific abstracts to reach its nearly 100 conclusions. The committee also proposed ways to expand and improve the quality of cannabis research efforts, enhance data collection efforts to support the advancement of research, and address the current barriers to cannabis research.

http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=24625

GOAL –
GET FAMILIAR WITH MEDICAL MARIJUANA

Recommended reading list - for all:

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

PSYCHIATRIC NEWS
AMERICAN PSYCHIATRIC ASSOCIATION

Daily and High-Potency Use of Cannabis Linked to Psychosis

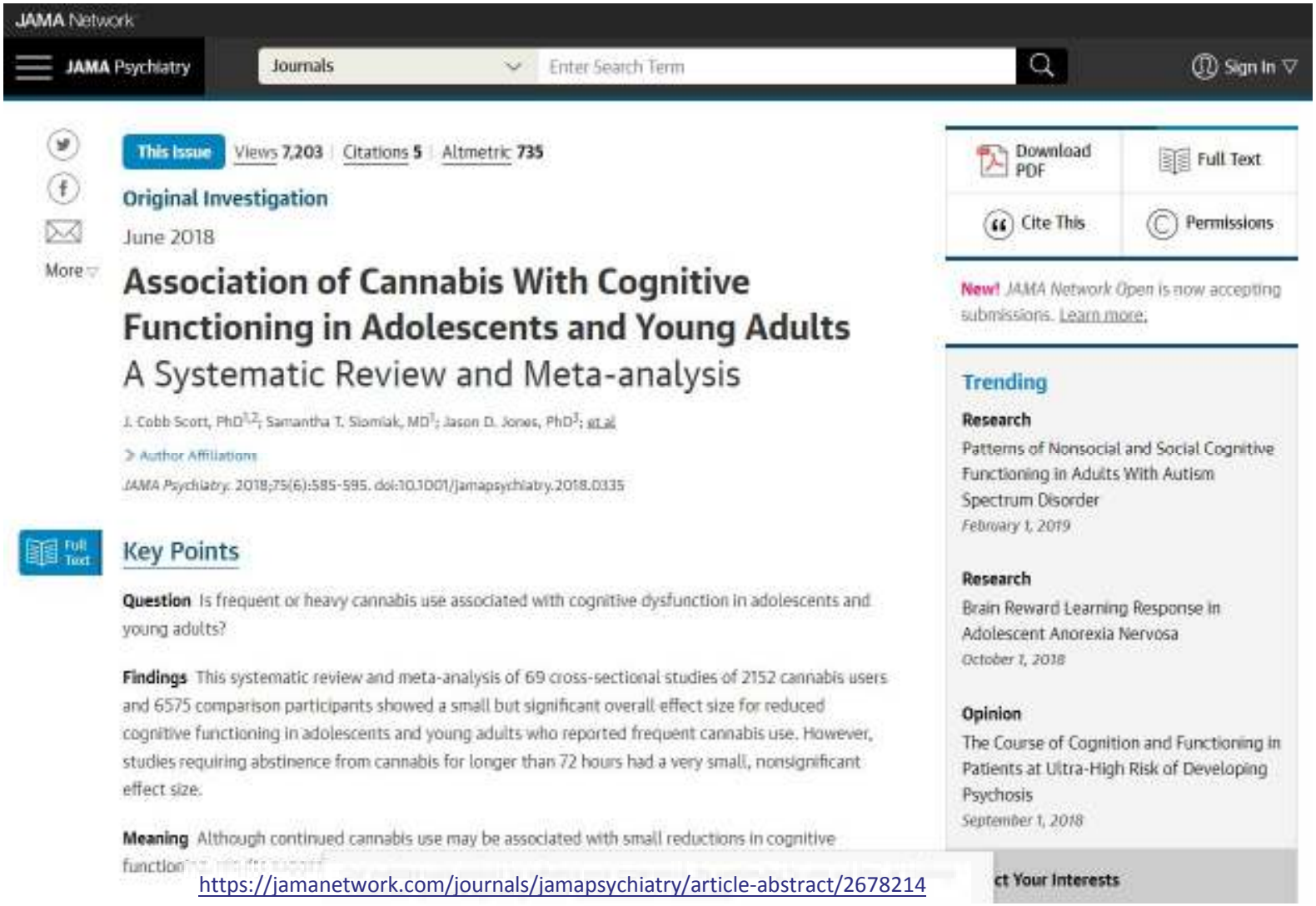
TERRI D'ARRIGO

Published Online: 16 May 2019 | https://doi.org/10.1176/appi.pn.2019.5a4

A multicenter study finds that risk increases threefold with daily use of cannabis and nearly fivefold when the cannabis has THC concentrations greater than 10%.

A study in *Lancet Psychiatry* reports that the risk of psychosis associated with cannabis is tied to daily use and the use of high-potency cannabis, namely cannabis with concentrations of delta-9-tetrahydrocannabinol (THC) greater than 10%. The study also paints a picture of how cannabis use influences rates of psychosis at a population level.

"We know that for alcohol or tobacco, the greater the consumption, the greater the harm; therefore, it is not surprising to see the same for cannabis—that more THC in the cannabis consumed has more effect on psychosis," said lead author Marta Di Forti, M.D., Ph.D., M.R.C., clinician scientist fellow in the Social, Genetic, and Developmental Psychiatry Centre at the Institute of Psychiatry, Psychology, and Neuroscience in London. "Although it was to be expected, it needed to be shown; and we could [show] it across several sites, making the findings more generalizable than



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Original Investigation

June 2018

Association of Cannabis With Cognitive Functioning in Adolescents and Young Adults

A Systematic Review and Meta-analysis

J. Cobb Scott, PhD[1,2]; Samantha T. Slomiak, MD[1]; Jason D. Jones, PhD[1]; et al

> Author Affiliations

JAMA Psychiatry. 2018;75(6):585-595. doi:10.1001/jamapsychiatry.2018.0335

Full Text

Key Points

Question Is frequent or heavy cannabis use associated with cognitive dysfunction in adolescents and young adults?

Findings This systematic review and meta-analysis of 69 cross-sectional studies of 2152 cannabis users and 6575 comparison participants showed a small but significant overall effect size for reduced cognitive functioning in adolescents and young adults who reported frequent cannabis use. However, studies requiring abstinence from cannabis for longer than 72 hours had a very small, nonsignificant effect size.

Meaning Although continued cannabis use may be associated with small reductions in cognitive function

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Trending

Research
Patterns of Nonsocial and Social Cognitive Functioning in Adults With Autism Spectrum Disorder
February 1, 2019

Research
Brain Reward Learning Response in Adolescent Anorexia Nervosa
October 1, 2018

Opinion
The Course of Cognition and Functioning in Patients at Ultra-High Risk of Developing Psychosis
September 1, 2018

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https://jamanetwork.com/journals/jamapsychiatry/article-abstract/2678214

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More

Original Investigation

February 13, 2019

Association of Cannabis Use in Adolescence and Risk of Depression, Anxiety, and Suicidality in Young Adulthood

A Systematic Review and Meta-analysis

Gabriella Gobbi, MD, PhD[1]; Tobias Atkin, BA[1]; Tomasz Zytynski, MD[1]; et al

Author Affiliations

JAMA Psychiatry. 2019;76(4):426-434. doi:10.1001/jamapsychiatry.2018.4500

Related Articles

Full Text

Key Points

Question Is adolescent cannabis consumption associated with risk of depression, anxiety, and suicidality in young adulthood?

Find

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New! *JAMA Network Open* is now accepting submissions. Learn more.

Trending

Research

Association of a Youth-Nominated Support Team Intervention With Mortality

May 1, 2019

Research

Effect of Augmenting Standard Care for Military Personnel With Brief Caring Text Messages for Suicide Prevention

May 1, 2019

Research

Prenatal Cannabis Exposure and Psychosis Proneness in Children

March 27, 2019

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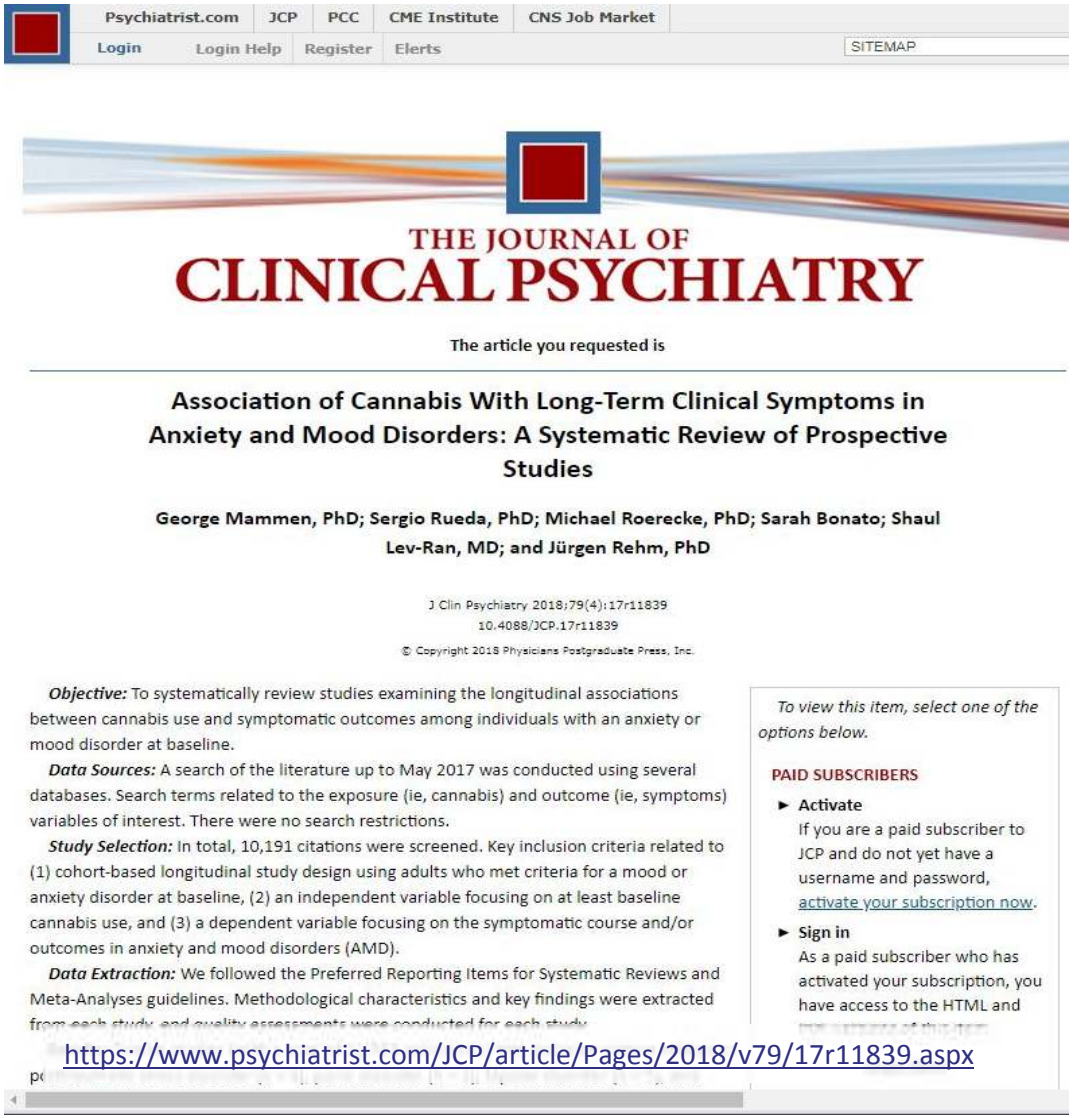
https://jamanetwork.com/journals/jamapsychiatry/article-abstract/2723657



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THE JOURNAL OF CLINICAL PSYCHIATRY

The article you requested is

Association of Cannabis With Long-Term Clinical Symptoms in Anxiety and Mood Disorders: A Systematic Review of Prospective Studies

George Mammen, PhD; Sergio Rueda, PhD; Michael Roerecke, PhD; Sarah Bonato; Shaul Lev-Ran, MD; and Jürgen Rehm, PhD

J Clin Psychiatry 2018;79(4):17r11839
10.4088/JCP.17r11839

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Objective: To systematically review studies examining the longitudinal associations between cannabis use and symptomatic outcomes among individuals with an anxiety or mood disorder at baseline.

Data Sources: A search of the literature up to May 2017 was conducted using several databases. Search terms related to the exposure (ie, cannabis) and outcome (ie, symptoms) variables of interest. There were no search restrictions.

Study Selection: In total, 10,191 citations were screened. Key inclusion criteria related to (1) cohort-based longitudinal study design using adults who met criteria for a mood or anxiety disorder at baseline, (2) an independent variable focusing on at least baseline cannabis use, and (3) a dependent variable focusing on the symptomatic course and/or outcomes in anxiety and mood disorders (AMD).

Data Extraction: We followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. Methodological characteristics and key findings were extracted from each study, and quality assessments were conducted for each study.

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https://www.psychiatrist.com/JCP/article/Pages/2018/v79/17r11839.aspx

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6312155

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

LIABILITY OVERVIEW: MEDICAL MALPRACTICE LAWSUITS

Currently, no ***reported*** med mal cases

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

LIABILITY OVERVIEW: MEDICAL MALPRACTICE LAWSUITS

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

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

LIABILITY OVERVIEW: OTHER LAWSUITS

- Criminal fraud
  - Defense = immunity re: professional opinion
  - AZ Supreme Court:
    - No immunity for lying about reviewing patient's medical records for the preceding 12 months
  - RM TIP: Don't lie and certify you did things that you didn't do!

State v. Gear, Supreme Court of Arizona, May 6, 2016

LIABILITY OVERVIEW: OTHER LAWSUITS

- Patient alleged statutory violation
  - Statute said that a registered patient's use of medical marijuana will not disqualify that patient from medical care
    - MD terminated treatment with patient because MD believed clinically contraindicated in terms of his treatment
    - Patient sued MD
  - AZ Court of Appeals:
    - Affirmed trial court's dismissal – no private right of action in statute
    - Specifically said patient could file a board complaint!
  - RM TIP: Document your clinical basis for termination – not just that patient is using medical marijuana

Gersten v. Sun Pain Mgmt., LLC, Court of Appeals of Arizona, April 18, 2017

LIABILITY OVERVIEW: OTHER LAWSUITS

- Licensing board alleged many violations, including that MD had signed certifications without seeing the patients
  - ALJ recommended against discipline
    - Board rejected
  - MD appealed to MI Court of Appeals
    - Confirmed board's discipline
    - Relied on guidelines from ASAM and FSMB
    - Board appealed Patient alleged statutory violation
  - RM TIP: Be aware of and follow guidelines

In re Proctor, Court of Appeals of Michigan, March 14, 2019

LIABILITY OVERVIEW: MEDICAL MALPRACTICE INSURANCE

Professional liability insurance

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

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Regulatory Agencies

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DORA summarily suspends four Colorado physicians

DENVER (July 19, 2016) - The Colorado Medical Board summarily suspended the licenses of four Colorado physicians, meaning they may not practice medicine in Colorado unless or until such time as the suspension is lifted by the Board. The Colorado Medical Board resides within the Division of Professions and Occupations (DPO), part of the Department of Regulatory Agencies (DORA).

According to the Orders of Suspension, the Board found reasonable grounds to believe that the public health, safety or welfare imperatively requires emergency action and/or that the Respondents were guilty of a deliberate and willful violation of the Medical Practice Act, the state law that regulates the practice of medicine in Colorado. All four physicians were recommending the medical use of marijuana, each authorizing high plant counts (e.g., the possession of at least 75 plants) for hundreds of individuals without medical necessity. The Board found such conduct falls below generally accepted standards of medical practice and violates § 12-36-117(1)(p) and (mm), C.R.S. and Colo. Const. art. XVIII, § 14(4).

The Board summarily suspended the medical licenses for the following physicians.

- Gentry Dunlop M.D., recommended the medical use of marijuana, which authorized the possession of at least 75 plants for at least 700 individuals without medical necessity.
- Robert Maiocco, M.D., recommended the medical use of marijuana, which authorized the possession of at least 75 plants for at least 190 individuals without medical necessity.
- Deborah Parr, M.D., recommended the medical use of marijuana, which authorized the possession of at least 75 plants for at least 300 individuals without medical necessity.
- William Stone, D.O., recommended the medical use of marijuana, which authorized the possession of at least 75 plants for at least 400 individuals without medical necessity.

https://www.colorado.gov/pacific/dora/DORA-summarily-suspends-four-physicians-medical-marijuana

LIABILITY OVERVIEW: LICENSING BOARD ACTIONS

MANY reported cases

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

LIABILITY OVERVIEW: LICENSING BOARD ACTIONS

OR SEEING PATIENTS AT HOTELS??

- Per the ME Medical Board:
  - MD, along with his wife and daughter, held "medical seminars" at 2 hotels over 2 days
  - Records failed to show examination was performed
  - At a minimum, on March 20th, MD would have had 6 lecture sessions (= 4 hours)
    - AND would have spent 22 hours with patients individually that date
- MD admitted to unprofessional conduct, based on:
  - Manner and location of the medical marijuana clinics
  - Failure to create and maintain adequate records
- Reprimand, fine ($2K), and reimbursement of Board's costs

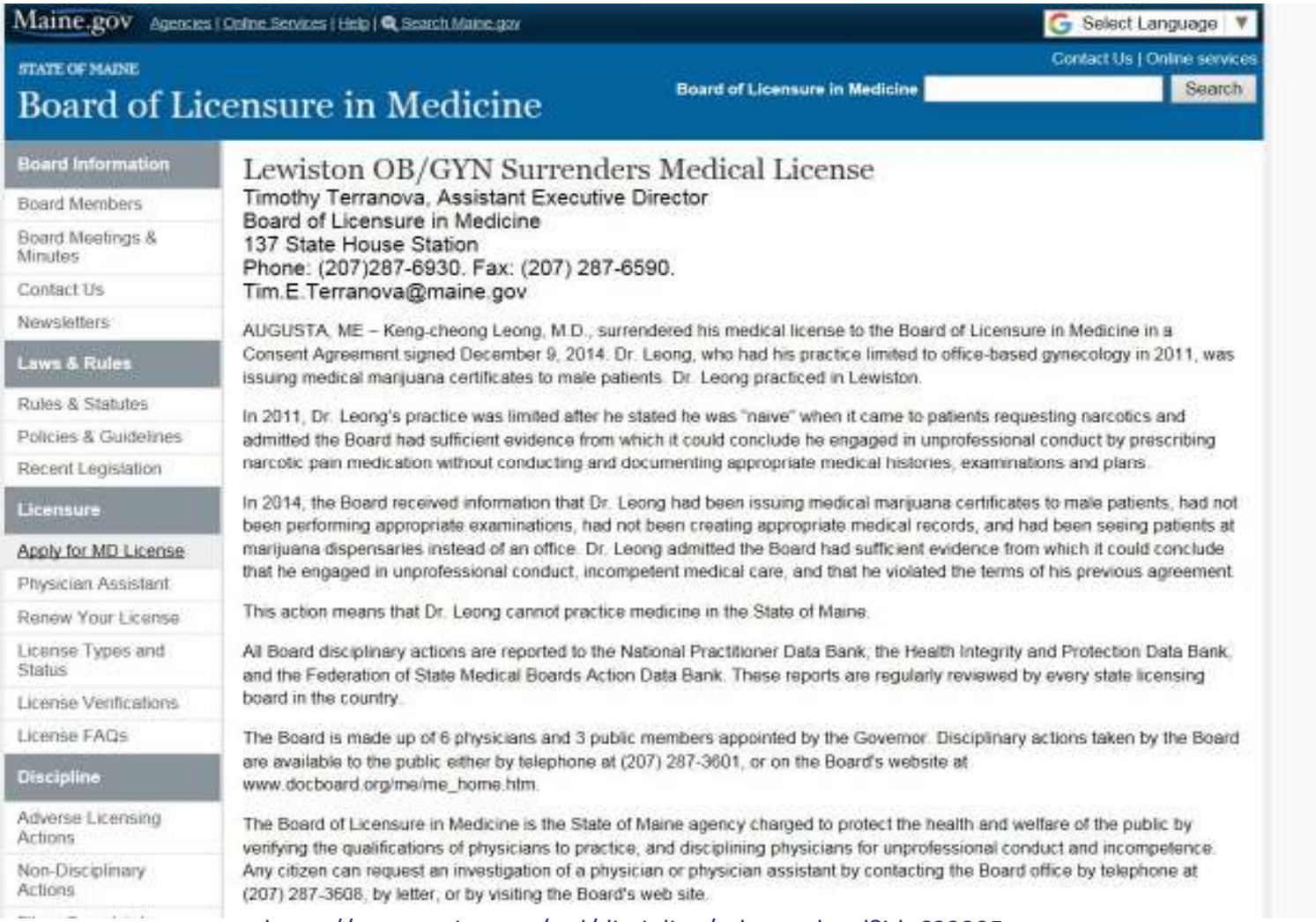
www.pfr.maine.gov/ALMSOnline/ALMSQuery/ShowCaseDetail.aspx?DetailToken=7B2D0BEBD9F5FAB71BD1AA28EE91D99B87C729CDF917A5166C0D13807F0CA93F

LIABILITY OVERVIEW:
LICENSING BOARD ACTIONS - IMMUNITY

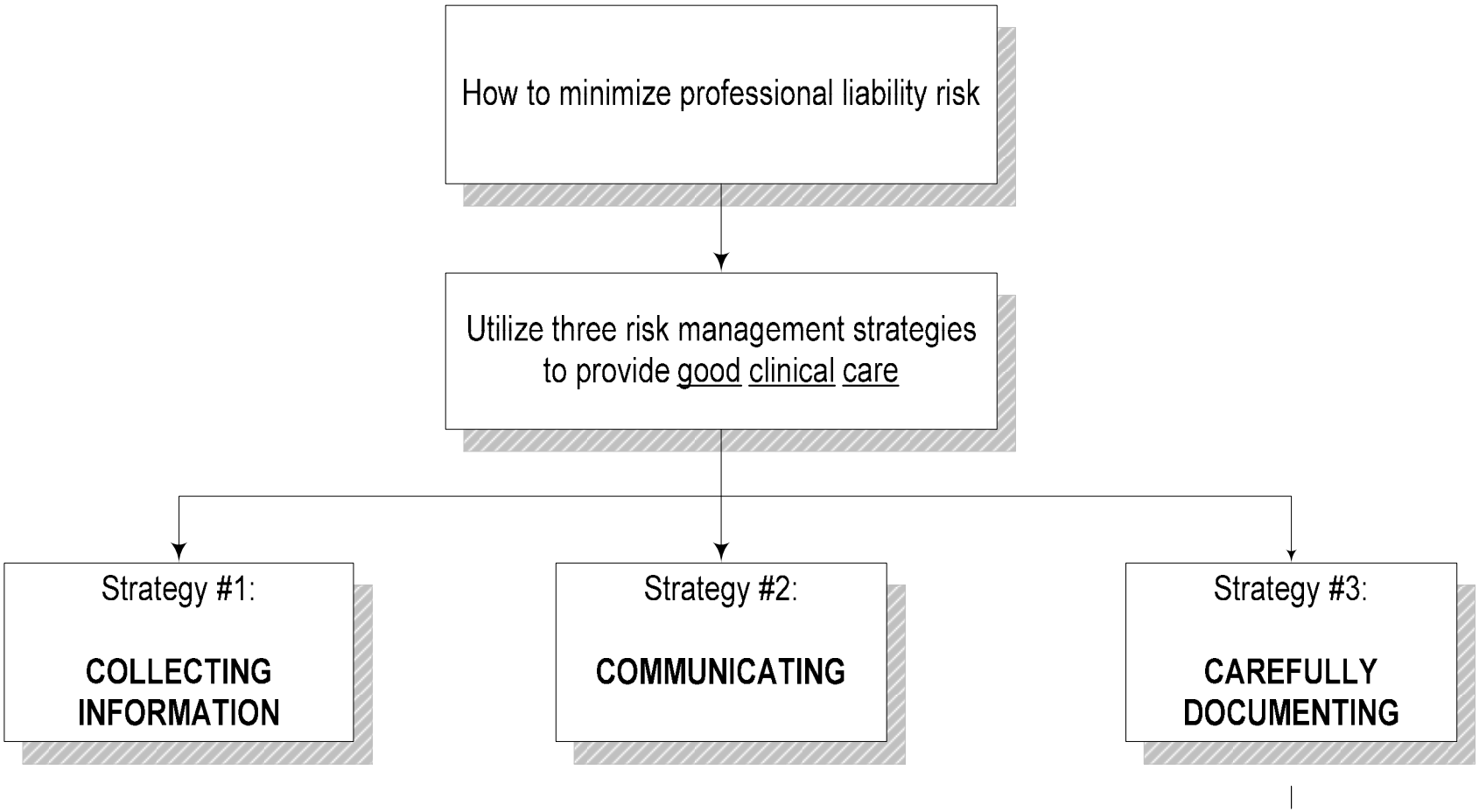
- CA Health & Safety Code § 11362.5(c):
  - "notwithstanding any other provision of law, no physician in this state shall be punished, or denied any right or privilege, for having recommended marijuana to a patient for medical purposes"

- BUT…"Respondent made a diagnosis without adequate basis, and without adequate research and study. He is not immunized for making a diagnosis that as grossly negligent. The immunity defense fails."

www2.mbc.ca.gov/BreezePDL/document.aspx?path=%5cDIDOCS%5c20190409%5cDMRAAAGL6%5c&did=AAAGL190409225003034.DID



https://www.maine.gov/md/discipline/releases.html?id=633295



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

Strategy #1: COLLECT INFORMATION

- About the patient
  - History
  - Examination
  - Check the PMP
- About the medication
  - Including APA statements
- About treatment standards
  - State
  - FSMB

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

Guidelines

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

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

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

Strategy #2: COMMUNICATE

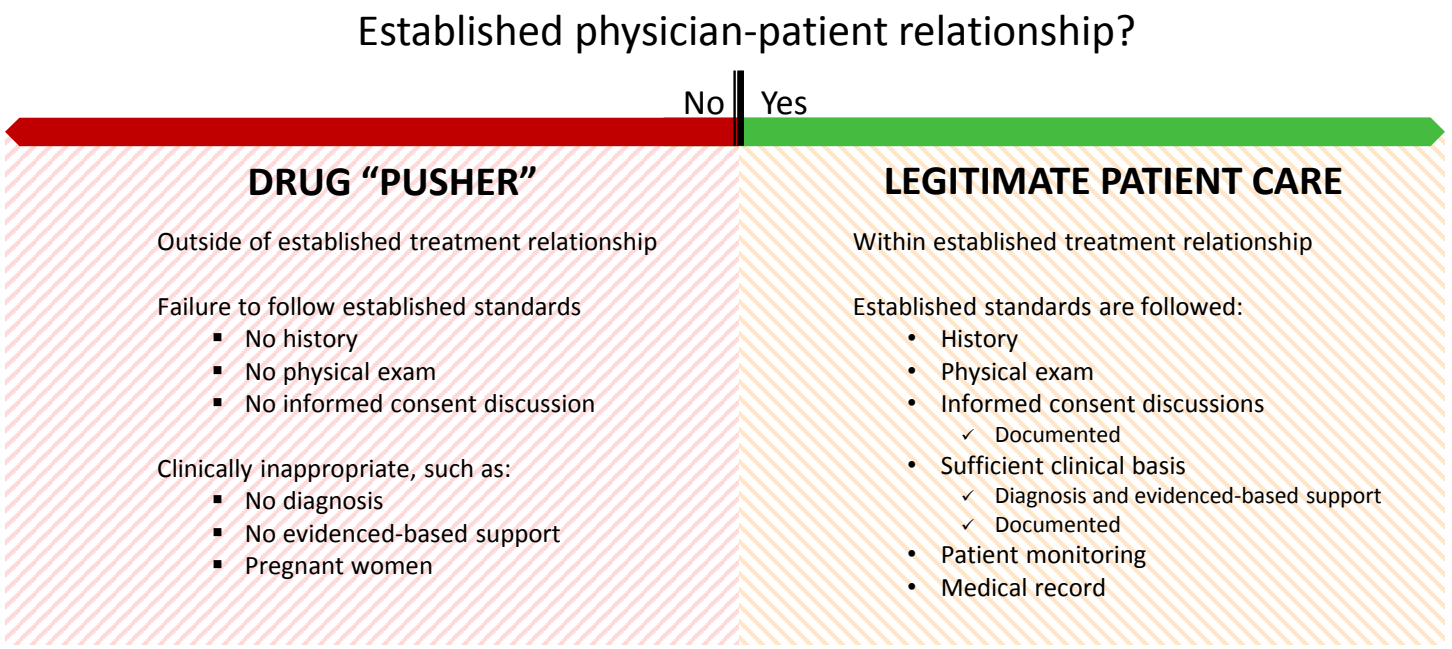
- With patient
  - Risks and benefits
    - Including risk of addiction
    - Side effects
  - Do not drive while intoxicated
- With others
  - Other prescribers

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

Strategy #3: CAREFULLY DOCUMENT

- Medical record
- Informed consent
- ? Treatment plan

Medical Marijuana Recommendations / Certifications



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TAKE AWAY POINTS

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

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

TAKE AWAY POINTS

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

QUESTIONS?