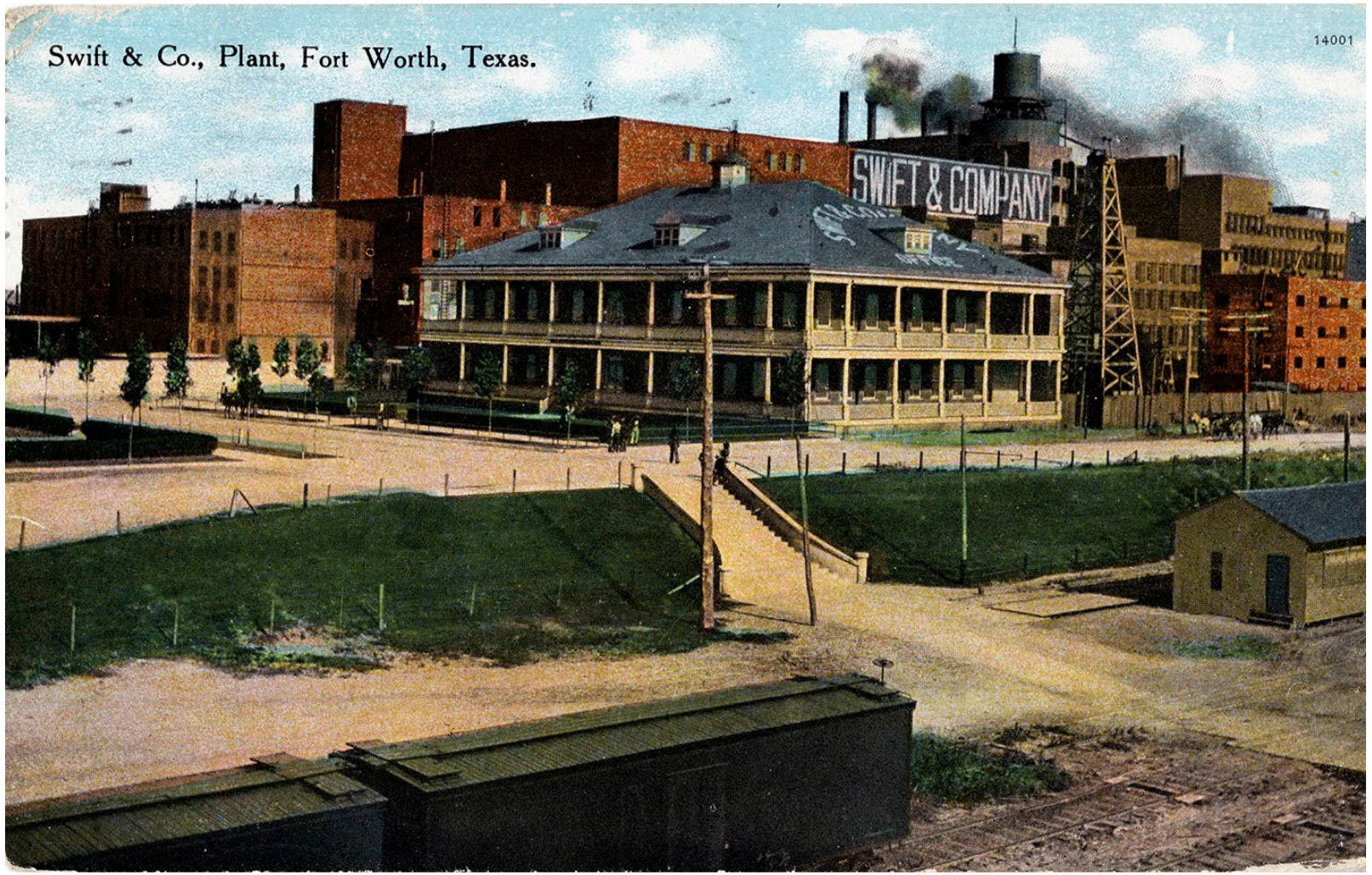
No Deference?

Healthcare Regulation and the Demise of *Chevron*

WhatleyKallas
Litigation & Healthcare Group

Olden Times

Skidmore v. Swift (1944)



Skidmore v. Swift (1944)

"We consider that the rulings, interpretations, and opinions of the Administrator under this Act, while not controlling upon the courts by reason of their authority, do constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance."

Skidmore v. Swift (1944)

"The weight of such a judgment in a particular case will depend upon the **thoroughness evident in its consideration**,

the **validity of its reasoning**,

its **consistency with earlier and later pronouncements**,

and **all those factors which give it power to persuade**, if lacking power to control."

Administrative Procedure Act

Chevron U.S.A. v. Natural Resources Defense Council (1984)

Chevron Two-Step

Step One: Has Congress "directly spoken to the precise question at issue"?

Yes: The court "must give effect to the unambiguously expressed intent of Congress"

No, the statute is silent or ambiguous: Go to Step Two

Step Two: Is the agency's action "based on a permissible construction of the statute"?

Major Questions Doctrine

FDA v.
Brown & Williamson
(2000)

King v. Burwell
(2015)

West Virginia v. EPA
(2022)

Did *Chevron* Matter?

Loper Bright Enterprises v. Raimondo

Loper Bright Enterprises v. Raimondo

"By forcing courts to instead pretend that ambiguities are necessarily delegations, *Chevron* does not prevent judges from making policy. It prevents them from judging."

Loper Bright Enterprises v. Raimondo

"[W]e do not call into question prior cases that relied on the *Chevron* framework. The holdings of those cases that specific agency actions are lawful—including the Clean Air Act holding of *Chevron* itself—are still subject to statutory *stare decisis* despite our change in interpretive methodology."

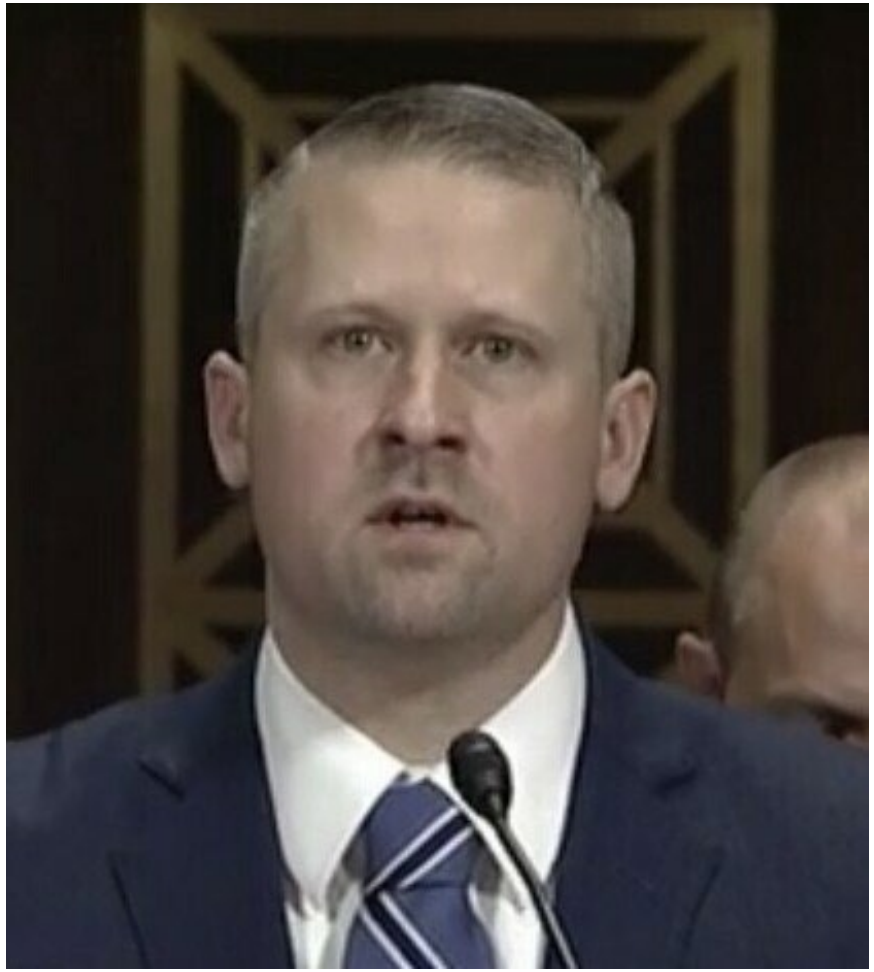
Loper Bright Enterprises v. Raimondo

"Under the Public Health Service Act, the Food and Drug Administration (FDA) regulates 'biological product[s],' including 'protein[s].' 42 U. S. C. §262(i)(1). When does an alpha amino acid polymer qualify as such a 'protein'? Must it have a specific, defined sequence of amino acids? *See Teva Pharmaceuticals USA, Inc.* v. *FDA*, 514 F. Supp. 3d 66, 79–80, 93–106 (DC 2020)."

Kagan, J., dissenting

Corner Post, Inc. v. Board of Governors

Nationwide Injunctions



AMA
AMERICAN MEDICAL ASSOCIATION

No Deference?

Health Care Regulation and the Demise of Chevron

ASMAC Fall Conference 2024

But is the sky really falling?

It isn’t clear…but what is clear is increased uncertainty and more litigation opportunities

Loper, Corner Post, Jarkesy, and West VA v EPA (2022) decisions collectively have changed the balance of power away from agencies

New Opportunities and Avenues for Advocacy Efforts

Congressional Advocacy

Agency Advocacy

Judicial Advocacy

Working with Congress

Courts will now decide whether Congress has explicitly delegated discretionary regulatory authority to an agency. Rules lacking clear direction from Congress may be more ripe for challenges. Legislative text must be more precise.

- **Opportunity:** Increased advocacy on favorable language
- **Downside:** Development of legislation and negotiations on final language may be more complex, take more time, fail

Working with Agencies

- Agencies will need to be more deliberate in writing regulations and implementing programs that will stand up against challenge

- There is a significant opportunity for attorneys for physicians, healthcare entities, medical societies to assist agencies through various interactions and submission of comments on new proposals to build a thorough record before the agency

- This will also require a review of existing problematic regulations and guidance to build a case for potential legal challenges

Advocacy in the Courts

- Do agency rules or actions create adverse impact? Do rules, guidance, program implementation exceed statutory authority or intent?

- Key questions to ask:
  - Is regulatory language consistent with statutory text?
  - Is the agency authorized to act?
  - Has the agency used reasoned decision-making?

Advocacy in the Courts

Identify possible regulatory pain points and Strategize on where to bring challenges

- Medicare: MIPS Quality Measures, MIPS Total Per Capita Cost Measure, other physician fee schedule issues
    - Note that many of the PFS and MIPS policies are precluded by statute from judicial review; is there any wiggle room?
- Medicare DSH
- Stark Self-Referral Law and Anti-Kickback Statute
- Physician-Owned Hospitals
- FDA Regulation of Laboratory-Developed Tests
- Mental Health Parity
- No Surprises Act
- Affordable Care Act Section 1557 Gender Identity Protection and other Social Policy Issues
- Affordable Care Act Coverage and Tax Credit Issues
- Public Health Issues (Climate Change)

Physicians' powerful ally in patient care

American Society of Medical Association Counsel

October 7, 2024
Chatham Bars Inn
Chatham, Massachusetts

The Supreme Court and Medicine: What's Happened, What's Next?

Leonard A. Nelson
AMA Senior Assistant General Counsel
Director, Litigation Center of the AMA and the State Medical Societies

A. What's Happened in the Supreme Court Regarding Medicine?

1. Murthy v. Missouri, 114 S.Ct. 1972 (6/26/2024)

Plaintiffs:	Two states and five social-media users
Defendants:	Surgeon General and other federal officials
Background:	The federal government urged/pressured social media companies to remove information from their websites concerning the COVID pandemic that the government deemed false and harmful to public health
Cause of Action:	Violation of Freedom of Speech
AMA Participation:	*Amicus* brief in support of federal government
Result:	Preliminary injunction against the federal government ordered vacated, as the plaintiffs lacked standing to sue for injunctive relief

2. FDA v. Alliance for Hippocratic Medicine, 602 U.S. 367 (6/13/2024)

Plaintiffs:	Pro-life physicians and advocacy organizations
Defendants:	FDA and other federal agencies
Background:	Plaintiffs preliminarily enjoined the FDA's approval of Mifepristone, a drug used to terminate pregnancies
Cause of Action:	Violation of APA, Pure Food and Drug Act
AMA Participation:	Multiple *amicus* briefs in support of FDA
Result:	Preliminary injunction reversed and remanded for lack of standing. Moral, ideological, and policy objections taken against persons other than the plaintiffs do not establish standing. A plaintiff cannot develop standing by spending money to gather information and advocate against government action. Doctors do not have standing to challenge government safety regulations simply because those regulations might require them to spend more time or money in their medical practices. An argument that no one has standing does not support standing for those who would not otherwise have it. Some issues are left to political and democratic processes.

3. United States v. Rahimi, 144 S.Ct. 1889 (6/21/2024)

Plaintiffs:	United States
Defendant:	Zackey Rahimi
Background:	Rahimi repeatedly assaulted his girlfriend. During one of their altercations, he shot his gun, although it is unclear whether he shot at the girlfriend or at a witness. A Texas state court entered a restraining order, which, *inter alia*, suspended his right to possess a gun. As a result of the spat with his girlfriend and numerous other acts of violence, many of which involved his use of firearms, the police searched Rahimi's residence, where they found a pistol, a rifle, ammunition, and a copy of the restraining order. Rahimi was indicted for violating 18 U.S.C. § 922(g)(8), which makes it illegal to possess a firearm while subject to a domestic violence restraining order. Rahimi moved to dismiss the indictment, asserting that the statute infringed the Second Amendment on its face. The Second Circuit so held and ordered the indictment dismissed.
Cause of Action:	Violation of 18 U.S.C. § 922(g)(8)
AMA Participation:	*Amicus* brief in support of federal government
Result:	Second Circuit reversed, and indictment against Rahimi reinstated. The statute is sufficiently similar to laws restraining firearm possession at the time of the Constitution to pass muster.

4. Garland v. Cargill, 602 U.S. 406 (6/14/2024)

Plaintiff:	Michael Cargill
Defendants:	Attorney General of the United States and the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF)
Background:	26 U.S.C. § 5845(b) prohibits private citizens from owning machineguns. A machinegun is defined as a weapon that can fire more than one shot by a single pull of the trigger. Following a mass shooting in Las Vegas but overturning contrary previous rulings, ATF published a regulation that classified semiautomatic rifles with bump stocks as machineguns. A bump stock is a device that can be affixed to a rifle and uses the recoil to enable the shooter to manipulate the trigger so that it is easier to fire multiple rounds. Cargill surrendered two bump stocks to ATF under protest. He then sued to challenge the regulation, asserting that it exceeded ATF's authority to prohibit machineguns.
Cause of Action:	Violation of APA, National Firearms Act
AMA Participation:	*Amicus* brief in support of federal government
Result:	Judgment in favor of Cargill and against ATF

5. Moyle v. United States, 603 U.S. _____ (6/27/2024)

Plaintiff:	United States
Defendants:	Speaker of the Idaho House of Representatives and State of Idaho
Background:	An Idaho law prohibits abortions unless necessary to prevent a pregnant woman's death, but without making an exception to prevent serious harm to the woman's health. The Idaho law was preliminarily enjoined in the lower courts.
Cause of Action:	Violation of Emergency Medical Treatment and Labor Act (EMTALA), which requires that Medicare-funded hospitals provide abortion services when needed to stabilize a medical condition that seriously threatens a pregnant woman's health
AMA Participation:	*Amicus* briefs (at the district court, the court of appeals, and the Supreme Court) in support of federal government
Result:	Writ of *certiorari* vacated as improvidently granted. Preliminary injunction against Idaho law stands.

B. What's Next in the Supreme Court Regarding Medicine?

1. Garland v. VanDerStok; No. 23-10718

Plaintiffs:	Individuals, companies, and associations
Defendants:	Attorney General of the United States and the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF)
Background:	The Federal Gun Control Act imposes licensing, recordkeeping, and serialization requirements on persons who deal in firearms. Firearms are defined as "any weapon" that can "expel a projectile by the action of an explosive." The question is whether an ATF regulation that deems a weapons parts kit that is designed to be converted into an operational firearm (a/k/a "a ghost gun") is valid. Set for argument on October 8, 2024
Cause of Action:	Violation of APA
AMA Participation:	*Amicus* brief in support of federal government

2. United States v. Skrmetti; No. 23-477

Plaintiffs:	Three transgender adolescents who live in Tennessee, their parents, and a Tennessee doctor who treats adolescents with gender dysphoria; also, the United States, through intervention
Defendants:	Tennessee officials responsible for enforcing Tenn. SB 1
Background:	Tenn. SB 1 prohibits medical treatments that allow a minor to maintain an identity inconsistent with the minor's "sex"
Cause of Action:	Equal Protection Clause
AMA Participation:	*Amicus* brief in support of federal government

FDA v. Wages and White Lion Investments; No. 23-1038

Plaintiffs:	Two manufacturers of electronic cigarettes
Defendant:	FDA
Background:	The FDA denied marketing approval for the plaintiffs' electronic cigarettes, finding that the denial was needed to protect public health
Cause of Action:	APA, Family Smoking Prevention and Tobacco Control Act
AMA Participation:	*Amicus* brief in support of federal government

Medical Malpractice Insurance: Association Opportunities

Robert John Kane
Illinois State Medical Society
&
ISMIE Mutual Insurance Company
Chief Legal Officer & Chief Compliance Officer

Brief History of Medical Societies and Tort Reform

- Commercial Insurance Companies withdraw from Market
  - >Late 1960s and early 1970s
  - >Mid 1980s to 1980s

- **Standard professional liability insurance -- claims made or occurrence**
- **Excess & surplus insurance coverage**
- **Alternative risk transfer market-captive (RRG, segregated cells)**

Medical Society Experience

>Professional liability insurance very scarce

>Physicians call on medical society to assist

>Societies endeavor to help

>Many societies create companies to cover member professional liability.

Illinois State Medical Society

- ISMS Insurance Services
- ISMS Inter-Insurance Exchange
- Mid 1980s “occurrence” to “claims made”
- Late 1990s conversion to mutual insurance company

MS & Insurance Company Agreements

- MS premium discounts
- MS IP royalty agreements
- Joint partnership drives-MS membership

Thank You

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Illinois State Medical Society
& ISMIE Mutual
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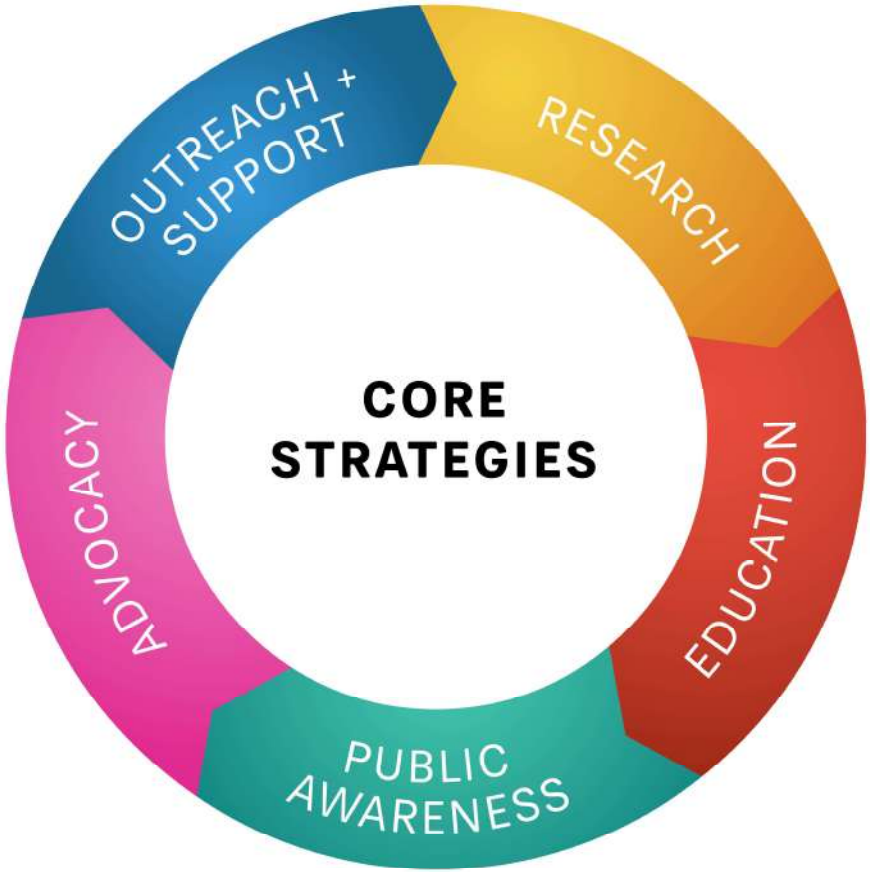
An Introduction to Suicide Prevention

American Foundation for Suicide Prevention

The American Foundation for Suicide Prevention's Talk Saves Lives™ is an educational presentation and is intended for informational purposes only. This presentation is not a substitute for professional medical advice or services. You should not use the information in this presentation for diagnosing or treating a health condition. You should consult a physician or other health care professional in all matters relating to your health, and particularly for any symptoms that may require diagnosis or medical attention. Any action on your part in response to the information provided in this presentation is at your discretion. The American Foundation for Suicide Prevention (AFSP) makes no representations or warranties with respect to any information offered or provided regarding treatment, action, or application of medication.

AFSP's mission is to save lives and bring hope to those affected by suicide.

For more, please see afsp.org



TALK SAVES LIVES


Mental Health Matters
90%
of people who died by suicide had a mental health condition at the time of their death.
However, most people with mental health conditions do not engage in suicidal behavior or die by suicide.
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Building a Culture that Addresses Suicide Prevention

- Universal education and health promotion
- Healthcare, schools, workplaces, etc.
- Changing social and cultural norms to decrease stigma and encourage help-seeking
- Prevention strategies for those who may be at increased risk
- Treatment and recovery
- Public policy

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What You Will Learn

By the end of this presentation, participants will be able to:

- Describe the impact of suicide
- Identify contributors to suicide and protective factors
- Understand how suicide may impact certain communities differently
- Describe how to recognize suicide warning signs
- Provide examples of how to start a conversation about suicide with someone you're concerned about
- List ways to seek and offer support and crisis resources for yourself or others

How We Talk Matters

Avoid saying:

Committed suicide • Failed or successful attempt

Say:

Died by suicide • Ended their life • Suicide attempt • Death by suicide

Common Terms:

- Suicide loss survivor
- Survivor of suicide loss
- Suicide bereaved
- Bereaved by suicide
- Lived experience
- Suicide attempt survivor

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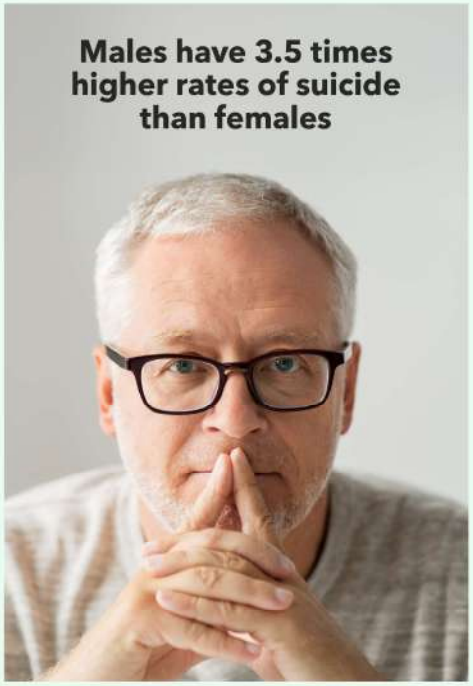
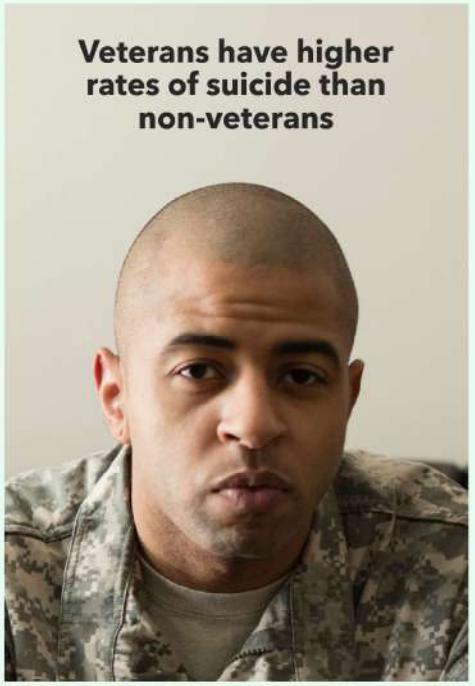
Scope of the Problem

- Suicide is a leading cause of death in the U.S.
- Each year, millions of people think about suicide
- There are well over a million people in the U.S. each year who survive a suicide attempt
- Most people have been affected by suicide in some way

Differences in Suicide Rates

Suicide rates may differ based on a variety of factors, including age, gender, geography, ethnicity, race and occupation.





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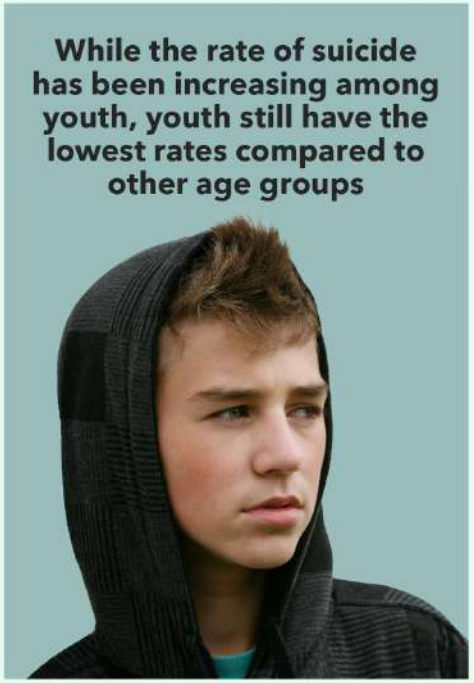
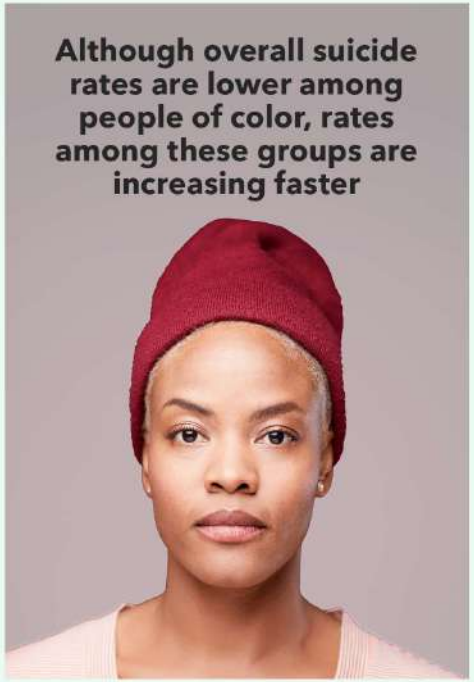
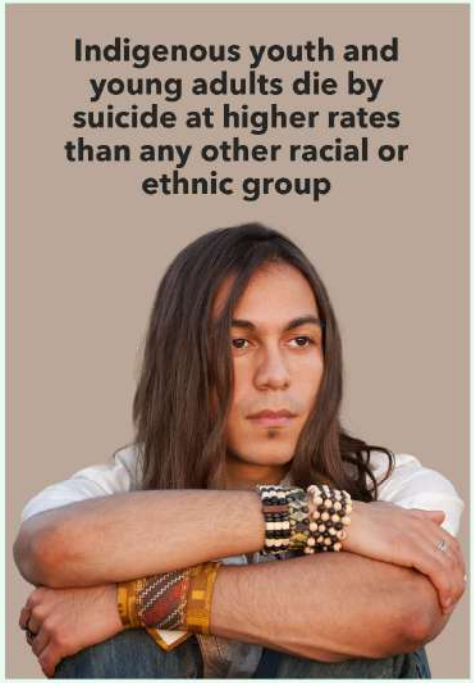
Differences in Suicide Rates (continued)







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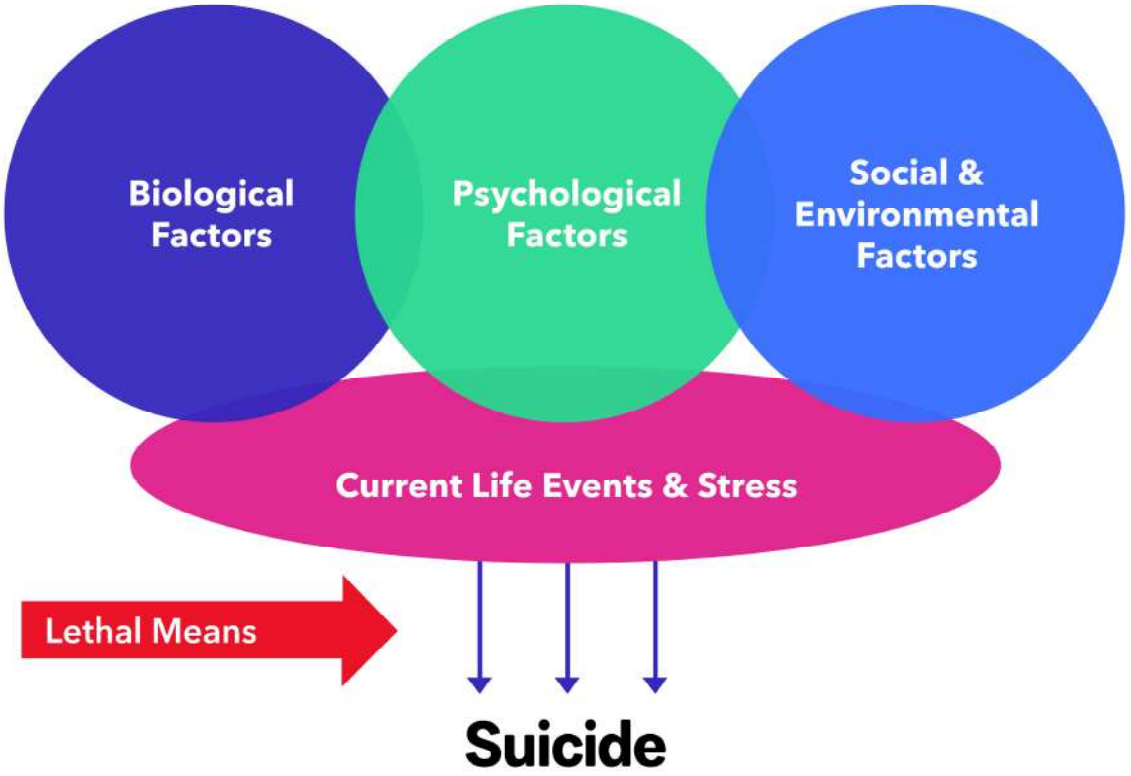
Interacting Risk and Protective Factors



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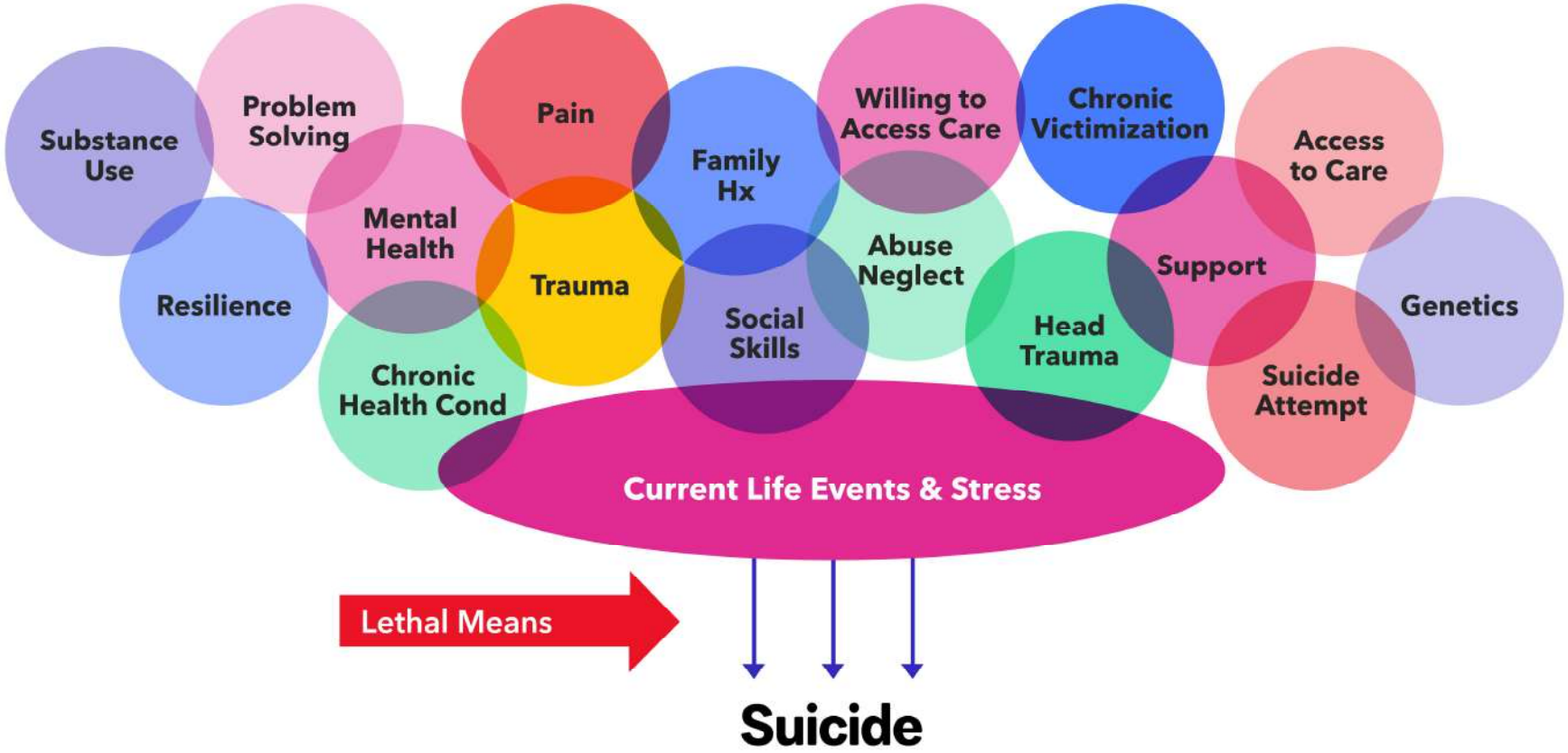
Moutier, C. Y., Harkavy-Friedman, J. M. (2018). Presented at the National Academy Sciences meeting on suicide prevention, Washington, DC.

Interacting Risk & Protective Factors



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Contributors to Suicidal Behavior

- Previous suicidal behavior
- Mental health conditions: depression, bipolar disorder, psychosis, personality disorders, eating disorders, substance use
- Physical health conditions, chronic pain
- Family history of mental illness or suicide loss
- Childhood trauma, abuse, neglect
- Traumatic brain injury
- Genetics
- Ongoing social factors: rejection, victimization, race or gender related discrimination, prejudice, systemic racism and historical trauma

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Protective Factors

- Resilience
- Strong sense of personal identity including gender, race, and ethnicity
- Social and problem-solving skills
- Connection
- Social support
- Willingness to participate in mental health care
- Access to mental health care

Certain groups and populations experience suicide risk factors and contributors differently

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Suicide and Healthcare Workers

The risk of suicide is higher for health care workers compared with non-health care workers in the U.S.

Contributors to suicide risk include:

- Untreated or inadequately managed health conditions
- Burnout, depression and other forms of distress
- Shift work
- Real and perceived barriers to help-seeking
- Access to lethal means (i.e., medications)

Encouraging help-seeking behaviors, reducing stigma, increasing resources, and having open conversations about mental health can protect against suicide.

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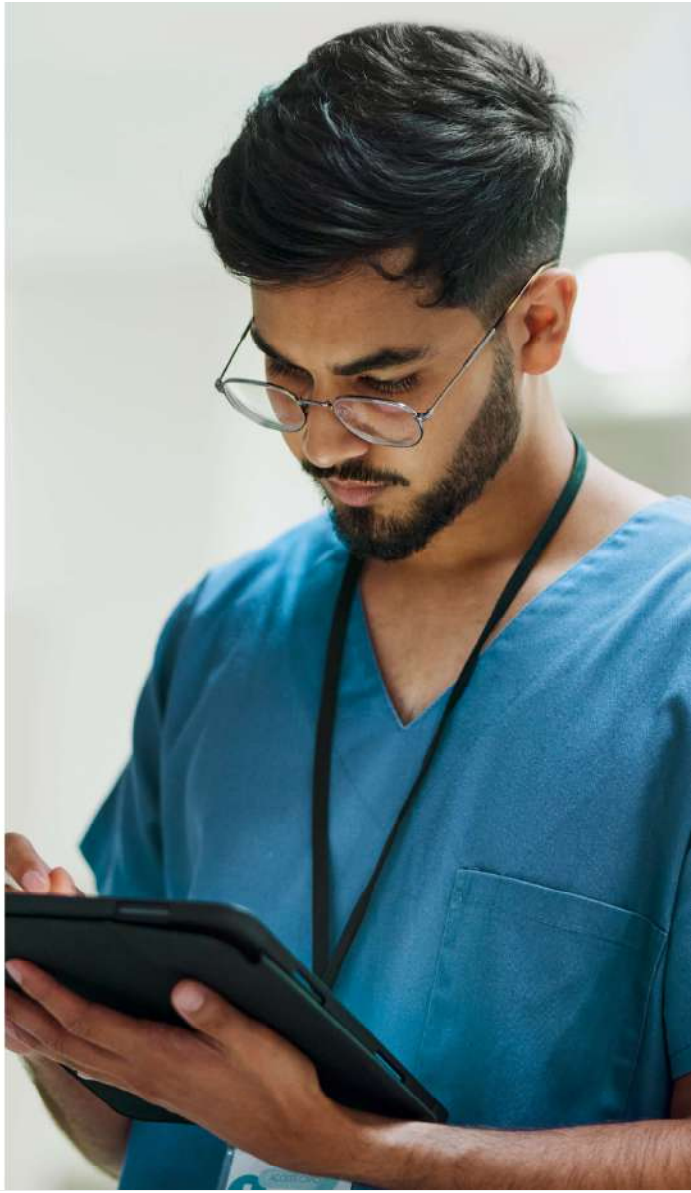

Thoughts of Suicide are Complex

- Part of them wants to live, part of them wants their pain to end
- They may think that if they weren't around, it would be better for their family and friends
- They may feel like a burden
- They may feel overwhelmed with hopelessness

Perspective of a Person in Crisis

- Experience a crisis point
- Unbearable physical or emotional pain that feels unescapable
- Their brain is operating differently; thinking lacks flexibility
- They can't access coping skills
- It's not a choice to feel this way

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Thoughts of suicide are often temporary. Keeping people safe and helping them feel supported can get them through those critical moments.

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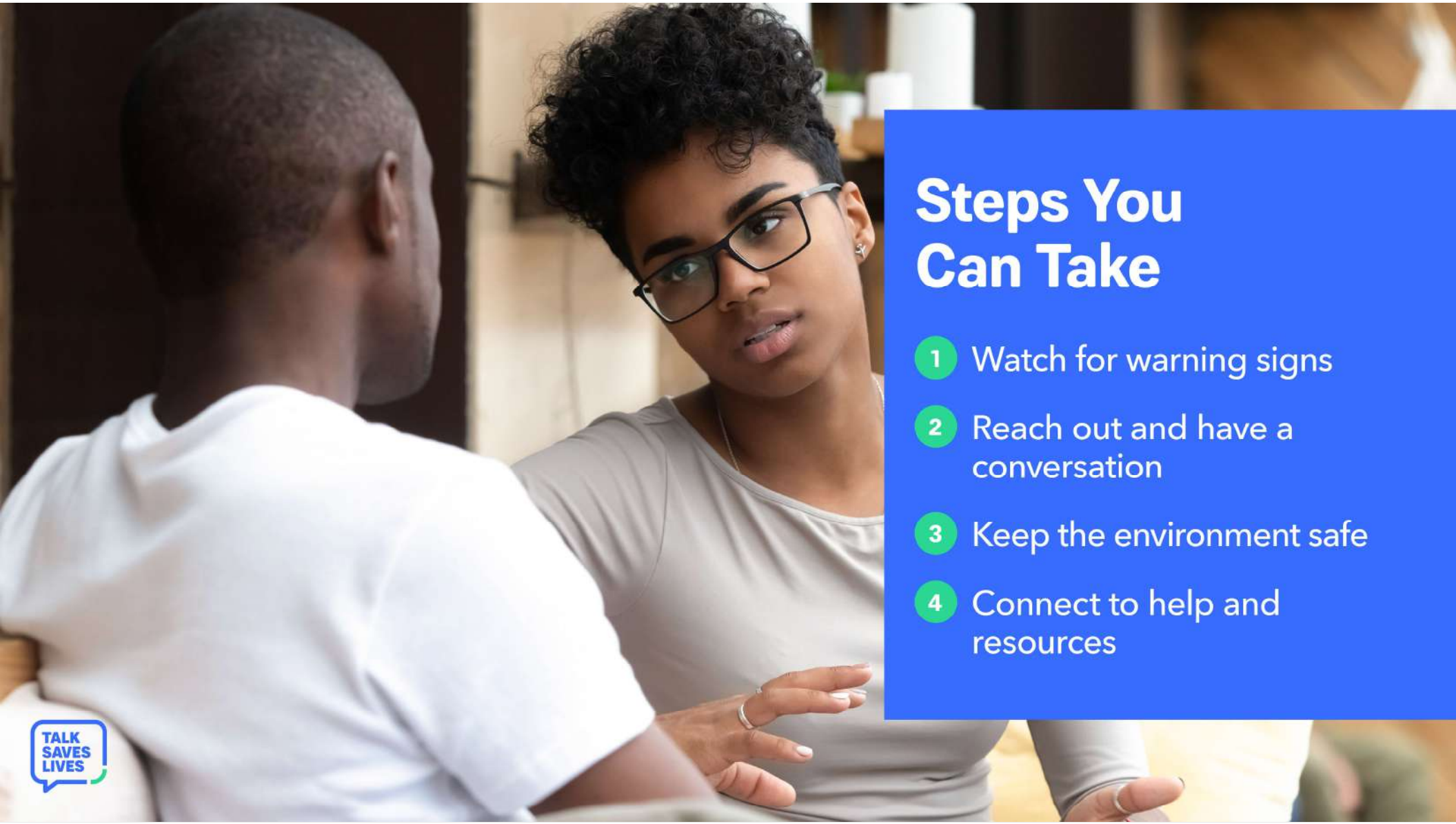
Steps You Can Take
1 Watch for warning signs
2 Reach out and have a conversation
3 Keep the environment safe
4 Connect to help and resources
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1 **Watch for Warning Signs**

Suicide Warning Signs

Talk

- Ending their lives
- Having no reason to live
- Feeling hopeless
- Being a burden to others
- Feeling trapped
- Unbearable pain

Behavior

- Increased use of alcohol or drugs
- Issues with sleep
- Acting recklessly
- Withdrawing from activities
- Isolating from family and friends
- Looking for a way to kill themselves
- Giving away possessions
- Missed work or declining work or school performance

Mood

- Depression
- Apathy
- Rage
- Irritability
- Impulsivity
- Humiliation
- Anxiety
- Sudden, unexplained happiness

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2 Have a Conversation

Have a Conversation

- Trust your instinct
- Assume you're the only one who is going to reach out
- Be okay with the awkwardness

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Workplace Leaders

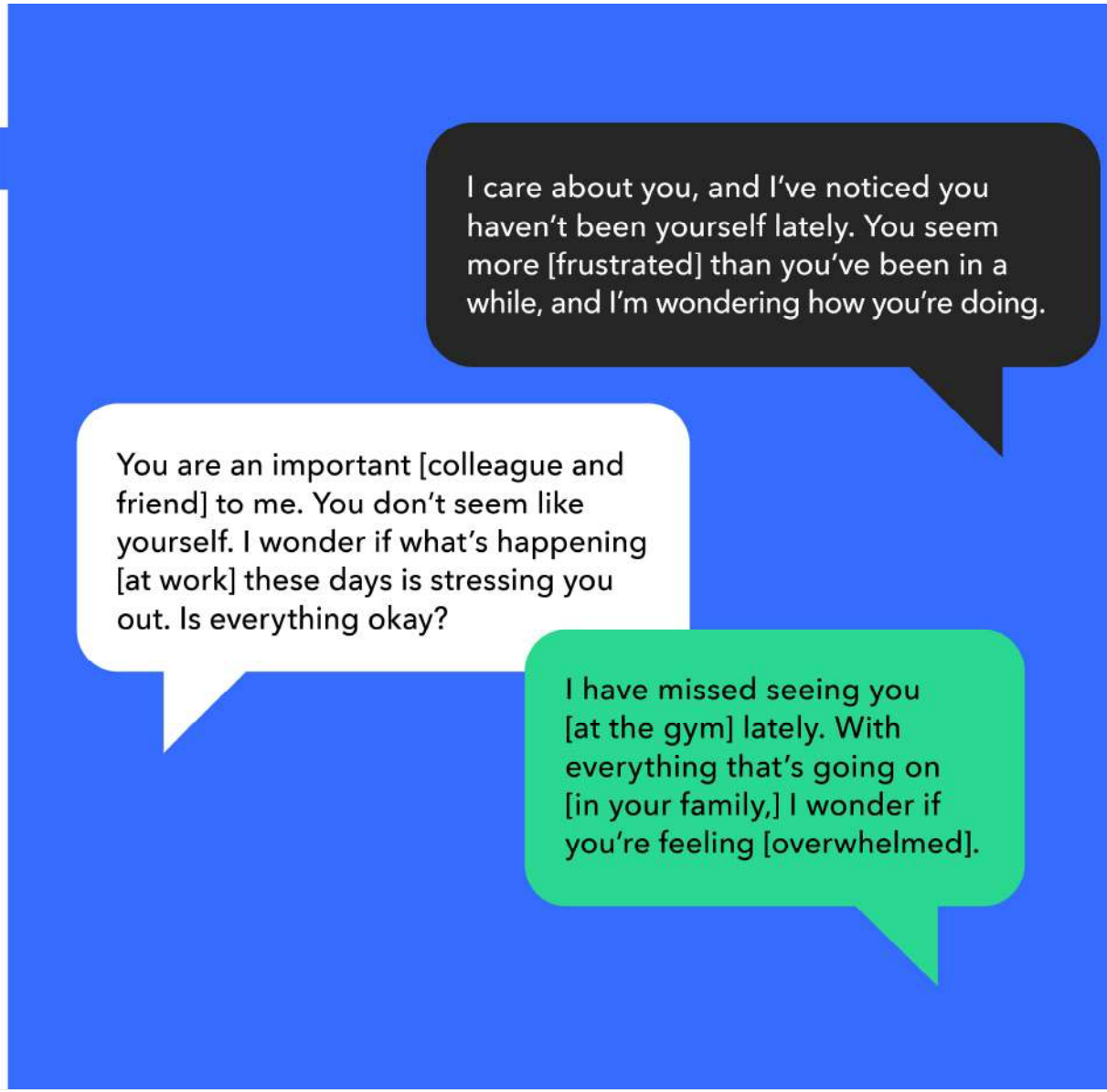
TALK
SAVES
LIVES

2 Have a Conversation

Reminders Before You Reach Out

- Avoid minimizing their feelings
- Avoid debating them that life is worth living
- Avoid offering advice on how to "fix" it

Remember, your role is to listen and help them connect to resources



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2 **Have a Conversation**

Listen with Empathy

- Ask open-ended questions and listen to their response
- Show empathy and support with your words and body language
- Listen for warning signs

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2 **Have a Conversation**

Ask Directly About Suicide

Research shows that asking about suicide does not put the thought in someone's head. Instead, it can bring relief and can be lifesaving.

You can start with:

> Sometimes when people feel like you do, they think of ending their life, are you having those thoughts?

It is important to ask the question directly:

> Are you thinking of ending your life?

> Are you thinking about suicide?

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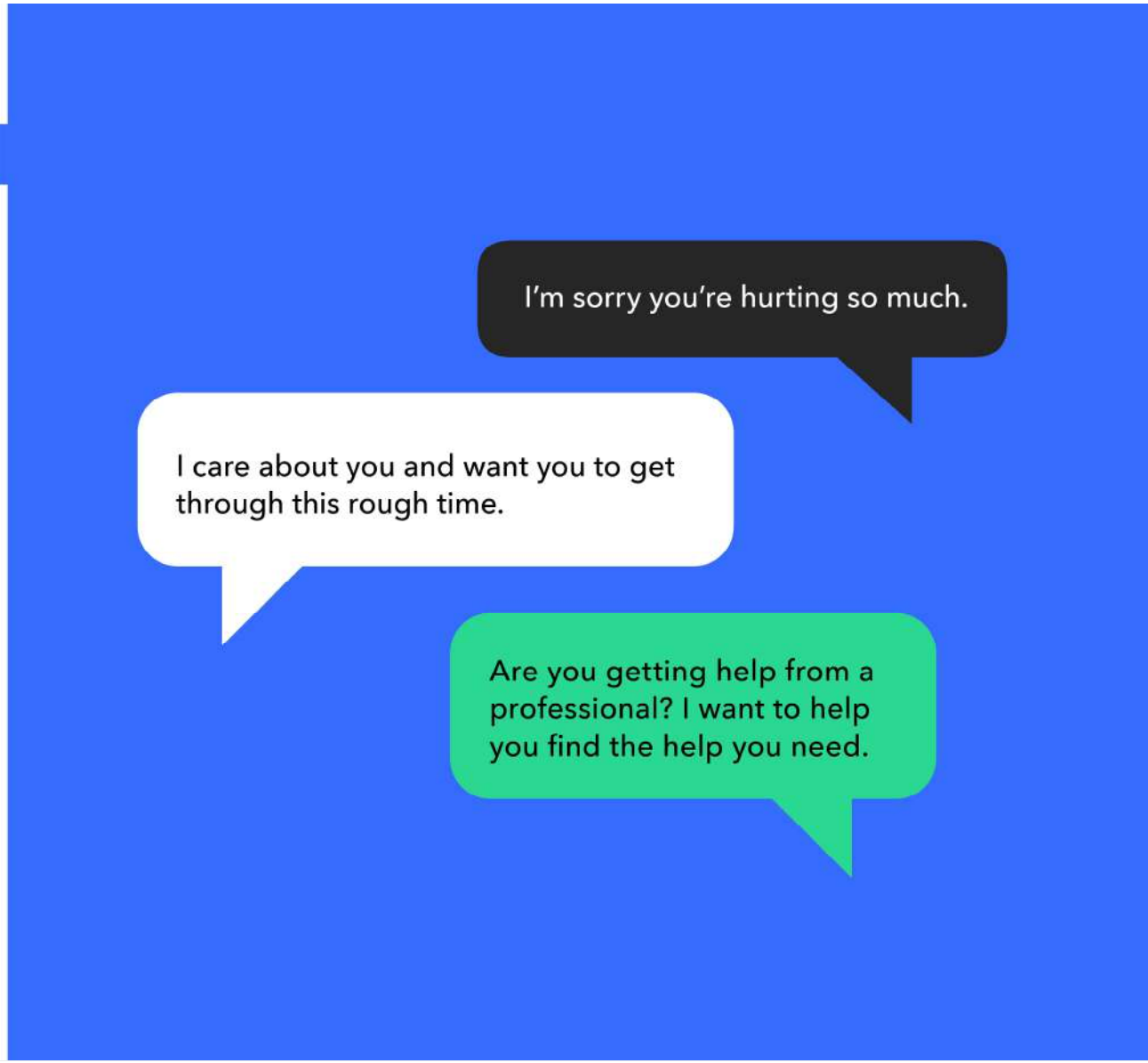
2 Have a Conversation

If they're not thinking about suicide, continue to listen and provide support



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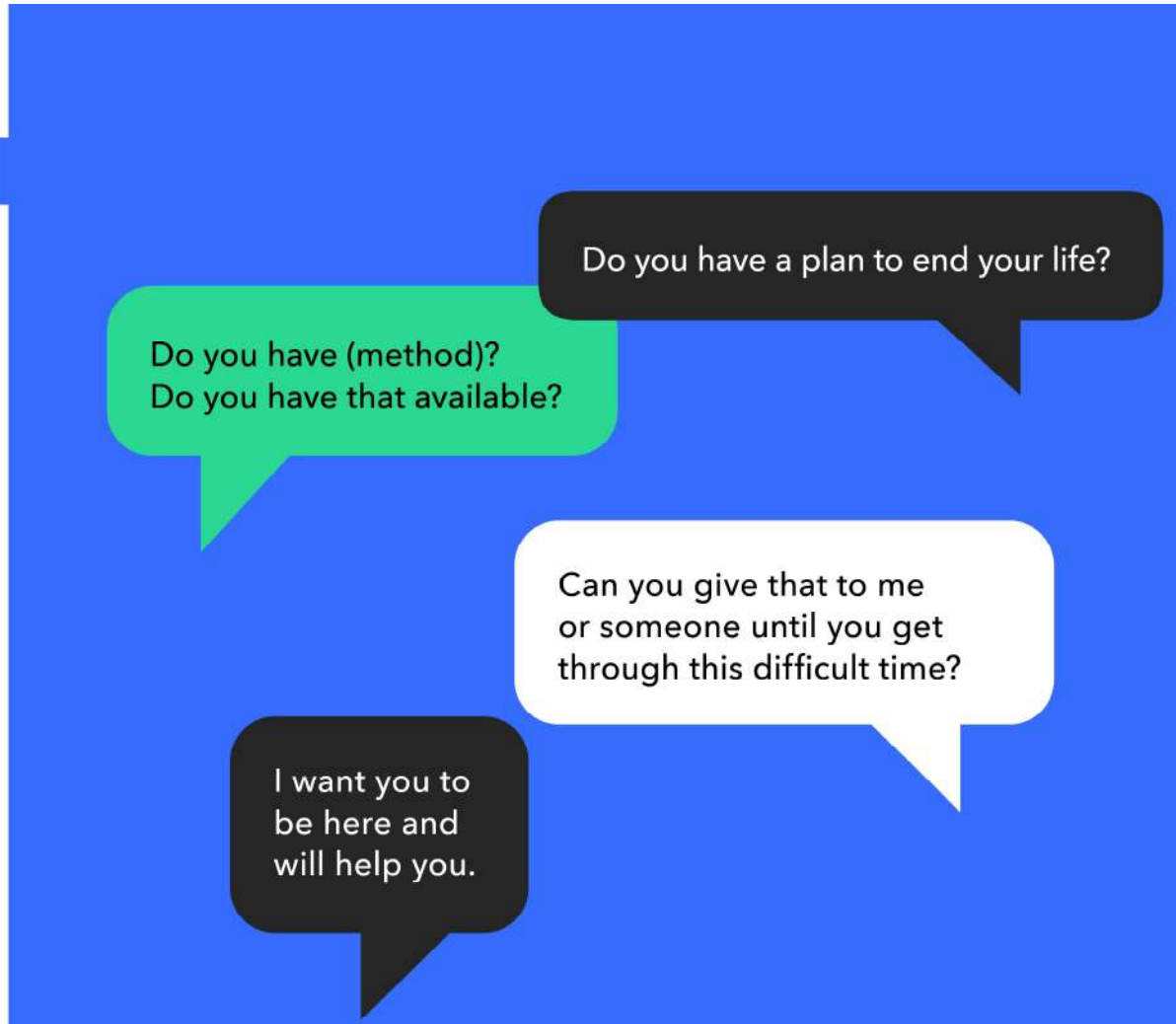
2 Have a Conversation

If they are thinking about suicide, find out more

Although a lot of feelings may come up if someone tells you they are thinking about suicide, it is helpful to learn more so you know how best to support them.



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2 **Have a Conversation**

Next Steps in the Conversation

- Thank them for sharing with you
- Remind them you are here for them
- Connect them with resources
- Stay in touch

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Example Conversation: Talk Away the Dark

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3 Keep the Environment Safe

The most important thing you can put between a person thinking about suicide and their way of ending their life is time.

Time allows the crisis to de-escalate and the opportunity for help.

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3 **Keep the Environment Safe**

Help them limit access to lethal means

Examples of how you might restrict lethal means:

- Remove or secure firearms, including decorative firearms (unloaded, locked, and disassembled)
- Store ammunition separately
- Secure medications including over the counter medications
- Secure toxic substances

Additionally, you can:

- Ask what they might need to feel safer
- Encourage them to refrain from substance use
- Encourage them to discuss keeping the environment safe with a mental health professional

"Lethal means" refers to a method that can be fatal if one uses it to attempt suicide.

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3 Keep the Environment Safe

Suicide and Firearms

- Nearly half of all U.S. households have at least one firearm
- In the U.S., around half of all suicides involve firearms
- In some states, firearms are used in as many as 70% of suicides
- Most firearm deaths are suicides in the U.S.
- If someone is at risk for suicide, having a gun in the house can be fatal

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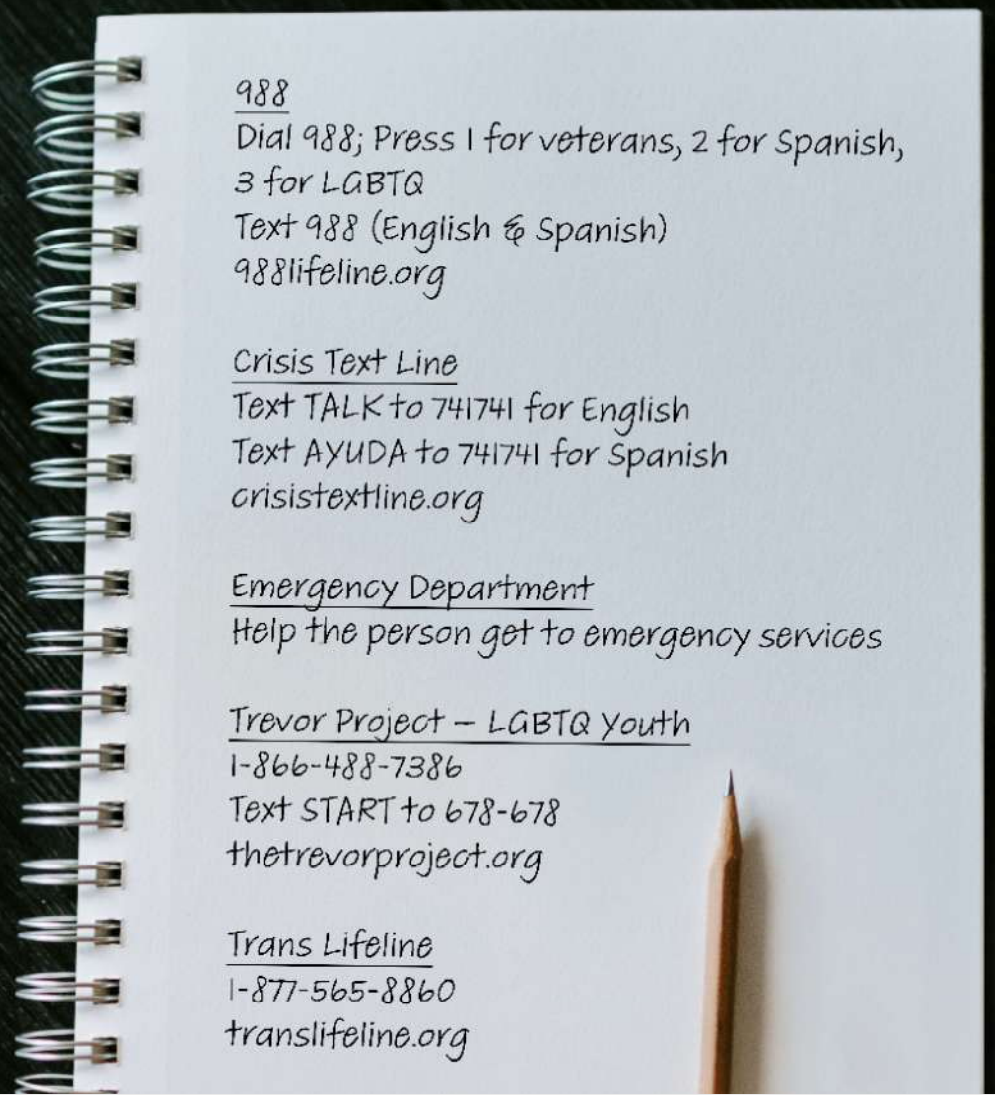
4 **Connect to Resources**

Crisis Resources

If someone has a suicide plan or is in a crisis and not safe, take immediate action.



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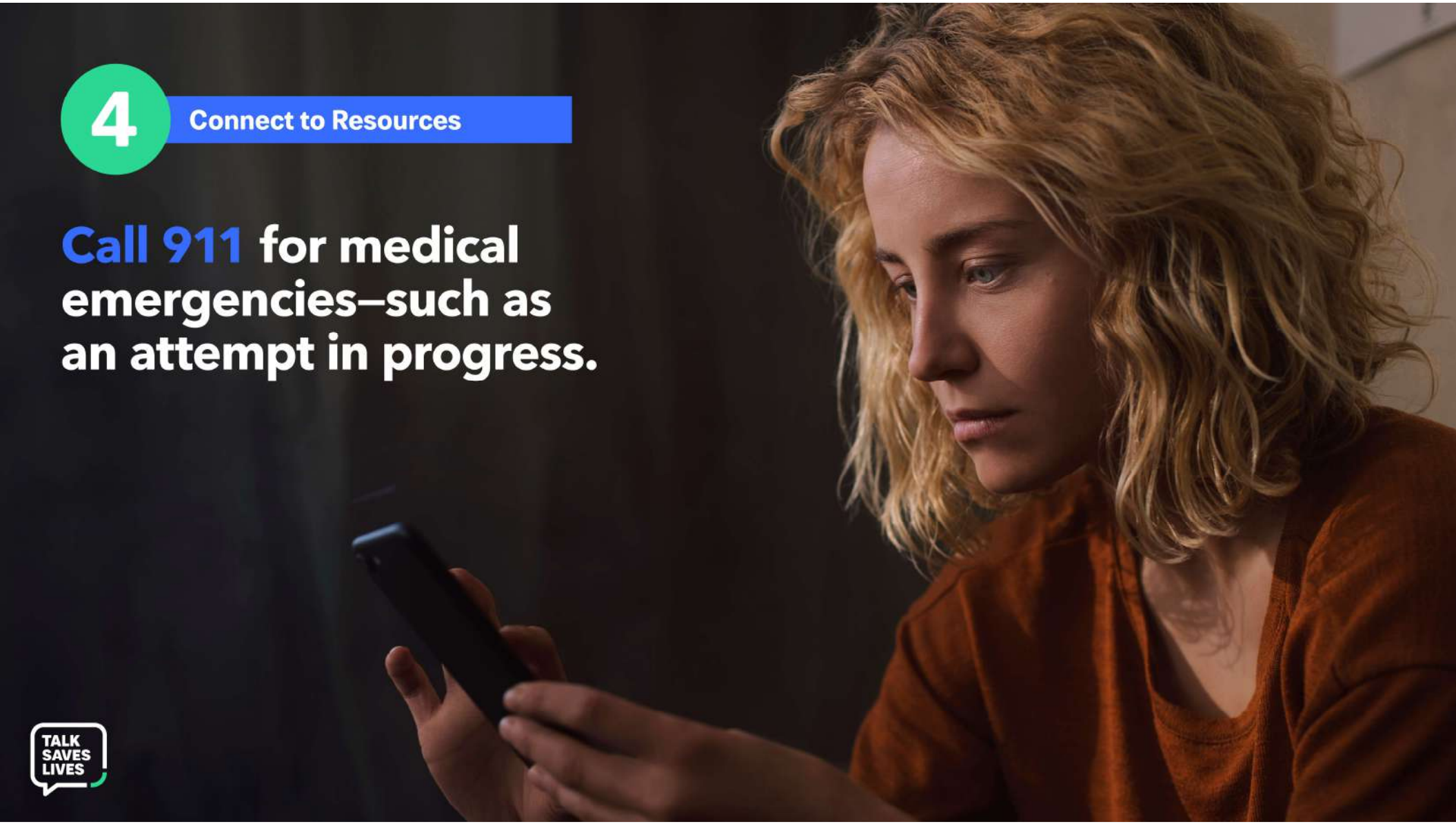
4
Connect to Resources
Call 911 for medical emergencies–such as an attempt in progress.
TALK SAVES LIVES

4 **Connect to Resources**

Connect to Professional Care

- Visit a mental health or medical provider who can help:
  - Findtreatment.samhsa.gov
  - Mentalhealthamerica.net/finding-help
  - inclusivetherapists.com
- Get an evaluation
- Discuss treatment options and interventions, such as safety planning, if applicable
- Continue treatment, follow up regularly
- Practice self-care and connect with loved ones and your community

We recognize there are many barriers to receiving mental health care, including a shortage of mental health professionals

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4 Connect to Resources

Postvention is Prevention: Resources

Providing support for loss survivors is important and is another way to prevent suicide. Resources include:

AFSP resources and programs available to help you heal
Afsp.org/loss and Afsp.org/get-help

The Dougy Center, The National Center for Grieving Children & Families
Dougy.org

Tragedy Assistance Program for Survivors (military or veteran)
TAPS.org/suicide

Alliance of Hope for Suicide Survivors
Allianceofhope.org

American Association of Suicidology
suicidology.org/resources/suicide-loss-survivors

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Prioritize Self-Care

Mind

Body

Soul

Surroundings

TALK SAVES LIVES

Summary: Lessons from Suicide Research

TALK SAVES LIVES

Together, we can create a culture that prioritizes mental health and suicide prevention.

Why is my Feedback Important?

- Your opinion and experiences are critical
- With your voice, we can better improve our programs
- Your feedback will help us know: Is the program working? What needs to be changed?
- Your feedback is confidential and will not be linked to you

Help us measure our impact by completing the post survey.

Visit afsp.org/TSLfeedback

TALK SAVES LIVES

Other Ways to Take Action to Prevent Suicide with Us

- Join your local Chapter
- Become an advocate
- Attend a training to become a volunteer presenter
- Walk in your community
- Partner to bring prevention to your community
- Sponsor an event
- Give a gift
- Engage with our social media accounts

Learn more at afsp.org
[editable link for chapter website]

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TALK
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LIVES

Follow us @afspnational

To learn more visit afsp.org/TalkSavesLives

American Foundation for Suicide Prevention

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Through the Looking Glass of the Corporate Practice of Medicine

Wes Cleveland, JD, American Medical Association
Mark Bonanno, JD, Oregon Medical Association
Jamie Ostroff, JD, California Medical Association

American Society of Medical Association Counsel
Fall Conference, October 8, 2024

Environmental Scan

- A hot issue and contentious for many federation organizations with physicians on both sides—intensity will increase.
- PE firms see health care investment as a growth opportunity, especially in fragmented sectors, e.g., independent physician practices (IPPs)-FTC v. U.S. Anesthesia Partners.
- IPPs may see PE investment as the only practical alternative to staying independent other than hospital or health insurer employment.
- Many factors necessitating need for investment: Medicare payments; Medicare payment differentials; monopsonistic private payers; health care consolidation; administrative burdens, e.g., PA, EHRs; inefficient quality reporting systems; burnout.
- AMA position: Middle of road reflecting physicians on both sides. However, recommended shift to a more negative position-BOT 9 Corporate Practice of Medicine Prohibition (I-24).

Regulatory Concern and Initiatives

- Anticompetitive impact: Increasing further consolidation in healthcare.
- May (in some cases) result in efficiencies but have detrimental impact, e.g., if PE firm closes one or more physician practices or health care facilities after purchase—shedding physicians and harming patient access.
- High profile events, e.g., Hahnemann Hospital in Philadelphia.
- Concern of FTC and DOJ: not strategic purchasers(?); FTC v. U.S. Anesthesia Partners (Welsh Carson); DOJ v. Change Healthcare (2022) (TPG); FTC Workshop on Private Equity in Health Care.
- State law activity: Colorado U.S.A.P settlement; notice or notice and approval: CA; CT; IL; IN; MA; MA; MN; NV; NY; OR; WA (and more proposed). NASHP model bill.

The Oregon Experience

- Status of corporate practice of medicine (CPOM) doctrine
- Permissive nature of the friendly PC legal concept
- Steady shift to physician employment
- Fairly rapid consolidation activity post-pandemic
- Legislative interest in addressing corporate control of medicine emerges

The Oregon Experience

- 2023 legislator-driven concept floated during session
  - House Bill 3574
  - Interim Hearing in Senate Health Care "Privatization in Health Care" 9/27/23
  - Speakers talk about cost, quality, access concerns
  - Explained limited legislative levers (e.g., mandate transparency, investigate anticompetitive conduct, prosecute fraudulent profiteering, preserve clinical autonomy)
- 2024 similar concept introduced as House Bill 4130
  - Complex bill in short session year (even years are five weeks)
  - Immediate reaction from industry

The Oregon Experience

- Basic mechanics of the bill
  - Redefined CPOM entities and added carve outs like hospitals, telemedicine
  - Applied CPOM doctrine in PC statute to LLC and LLP statutes
  - Attempted to limit control of PCs by MSOs
  - Attempted to limit dual ownership in PCs and MSOs
  - Established complaint process through Oregon Health Authority and Secretary of State targeted at PC
  - Expanded Medical Practices Act to address noncompete, nondisparagement, and nondisclosure restrictions
  - Included private right of action against PC about restrictive covenant violations

The Oregon Experience

- Changes to the bill and the hearing process
  - Early concept required attestation of physician in the PC
  - House versions included reporting requirements by PC not MSO, enforcement by dissolution of PC not MSO, limited where physicians could practice, expanded carved out entities, included unlevel playing field for noncompete restrictions, and lacked DOJ enforcement
  - Senate versions included private right of action against PC, unlevel playing field for noncompete restrictions, and lack of DOJ enforcement
  - Required two separate Senate committee hearings because first hearing did not allow sufficient testimony
  - Bill remained at Senate President's desk upon adjournment
- What is next for Oregon and OMA in 2025
  - Interim discussion sessions
  - Starting point could be HB 4130B, -15 with additional modifications
  - Awareness of AB 3129
  - Industry and PE lobbyists fully engaged

The California Experience

- Assembly Bill 3129 (Wood)
  - Requires notice and Attorney General approval for certain transactions involving private equity and health care providers
  - Codifies Medical Board guidance regarding California's ban on the corporate practice of medicine (CPOM)
- Parties
  - Private Equity Group (PEG) of hedge fund
  - Health care provider
    - Health Care facility (but not hospitals)
    - Provider (2-9 physicians)
    - Provider Group (10 or more physicians)

The California Experience

- Parties (con't)
  - Health Care Provider
    - Non-Physician Providers
    - Payor affiliated providers
- Transaction
  - Direct or indirect acquisition
  - Material amount of assets or operations
    - More than 15% of market value or ownership interest
    - Less than 15%, but involves supermajorty rights, veto rights, exclusivity, etc.
  - Change of governance or control

The California Experience

- AG approval required
  - Health Care Facility
  - Provider with gross annual revenue over $25 million
  - Provider group
  - Payor affiliated providers
- AG notice only
  - Non-physician provider with gross annual revenue over $4 million
  - Provider with gross annual revenue between $4 million and $25 million and not otherwise required to obtain AG consent

The California Experience

- Waivers
  - Operating cost exceeds operating revenue for 3 or more years and cannot pay debts
  - Risk of immediate business failure
  - Risk of Chapter 7 liquidation
  - Necessary to ensure continued access
  - Reasonable efforts made for alternate transactions
- Exceptions
  - Hospitals
  - Dermatology groups
  - University of California (limited)

The California Experience

- CPOM
  - Creates statutory prohibitions on PE or hedge fund actions that violate CPOM
  - Conduct previously only listed on medical board website as examples of improper conduct
    - Interference with professional judgment
    - Exercising control over certain actions

Discussion with panel and attendees

- We hear from some physician members that CPOM is not an important advocacy issue for them, how would you react to that?
- Is all of this legislative activity too little too late or do you see an advocacy path forward for the house of medicine?
- What are the legislative levers that make sense for navigating a rational approach to CPOM?

Thank you

- Wes Cleveland wes.cleveland@ama-assn.org
- Mark Bonanno mark@theoma.org
  - Resources in your packet (HB 4130B, Testimony)
- Jamie Ostroff jostroff@cmadocs.org
  - Resources in your packet (AB 3129)

Restrictive Covenants: Non-Compete, Non-solicitation, Non-Disparagement, Non-Disclosure and More

OUR PANEL

- Lauren Bailey, JD Louisiana State Medical Society
  - The Louisiana Approach
- Gene Ransom, JD, MedChi, Maryland Medical Association
  - The Maryland Approach
- Wes Cleveland, JD, American Medical Association
  - Different Approaches in the 50 States
- Rick Hindmand, JD, McDonald Hopkins, LLC
  - The FTC Rule
- Thomas Conley, JD, Saul Ewing, LLP
  - Non-Compete Alternatives
- Professor Richard Levenstein, JD (moderator), Nason Yeager, PA

The Louisiana Approach

- Senate Bill 165 was signed by Gov. Jeff Landry and becomes effective on January 1, 2025. It is not retroactive meaning that any contracts or agreements involving physicians that are entered into, renewed, or revised after this date will be subject to the new provisions outlined in the legislation.
- The Louisiana legislation specifically addresses the limitations placed on physicians regarding their ability to practice medicine within defined geographical areas for specified durations.

ACT 273 of the 2024 Regular Legislative Session

Primary Care Physicians in Louisiana

- Defined as those practicing predominately in family medicine, internal medicine, pediatrics, obstetrics, or gynecology.
- Post-termination restrictions apply only if the contract is terminated early, allowing a maximum of two years of non-practice in specified areas.
- Geographic limits restrict practice to the physician's principal parish and up to two contiguous parishes for two years post-termination.
- Non-compete clauses for primary care physicians cannot exceed three years from the initiation of the initial contract.

Other Physicians in Louisiana

- Non-compete clauses for other physicians can last a maximum of five years from the initiation of the initial contract.
- Geographic restrictions apply – within the principal parish and two contiguous parishes.
- If the contract is terminated early a two- year restriction may be enforced.

Louisiana Notes

Exemptions

- Physicians associated with rural hospitals and federally qualified healthcare centers in designated rural parishes are exempt from the non-compete restriction.

For existing contracts as of the law's effective date, the new terms start from January 1, 2025, requiring adjustments to accommodate the new provisions.

Contracts that Pre-Date the Law

MARYLAND LEGISLATION BANNING NON-COMPETE CLAUSES FOR HEALTH WORKERS

GENE M. RANSOM, MEDCHI – THE MARYLAND STATE MEDICAL SOCIETY

MedChi
The Maryland State Medical Society

House Bill 1388: Labor and Employment:

Noncompete and Conflict of Interest Clauses for Veterinary and Health Care Professionals and Study of the Health Care Market (passed). MedChi adopted a Resolution in the fall of 2023 supporting the elimination of non-compete clauses in physician contracts and limiting their scope, the result of years of work by the Restrictive Covenant Task Force within MedChi.

As introduced by Delegate/Dr. Terri Hill, this bill prohibited such clauses and was retroactive. MedChi and other health care professions strongly supported the bill.

THE PROCESS ALTERED THE LEGISLATION

- The Maryland House of Delegates removed the retroactivity clause because of constitutional concerns (the US Constitution prohibits the impairment of existing contracts) but passed the bill overwhelmingly, despite the objections of MedStar and the Maryland Hospital Association.
- In the Senate, the same entities pushed for amendments that banned noncompete clauses for those earning compensation less than $300,000 per year, but allowed them above that threshold, so long as the clause did not exceed 1-year and a 10-mile radius. Their amendments also sought a study of the effect of private equity firms buying physician practices and to delay implementation of the bill until July of 2025.

MedChi worked with Senate Finance (FIN) Committee Chair Pamela Beidle to modify the proposed amendments. Through our modifications, the bill measures the 10-mile radius from the primary place of employment, increases the salary threshold to $350,000, and expands the study to include all types of acquisitions of physician practices, including by hospitals.

The importance of this legislation to physicians cannot be overstated. While we would have preferred the bill as adopted by the House, not taking what is still a significant improvement over the current law posed unknown risks and would have allowed the opposition to mobilize their considerable resources heading into 2025.

With this result, physicians earning less than $350,000 cannot be subject to non-compete clauses at all, and those above that amount are protected from terms that are geographically overbroad (for example, when a hospital system measures the distance from ANY of its facilities in the State) and longer than 1-year.

FTC ACTION – MOST LIKELY WON'T MATTER IN MARYLAND

- The following outline provides a high-level overview of the FTC's proposed final rule:
- The final rule bans new noncompetes with all workers, including senior executives after the effective date.
  - Specifically, the final rule provides that it is an unfair method of competition—and therefore a violation of Section 5 of the FTC Act—for employers to enter into noncompetes with workers after the effective date.
- For existing noncompetes, the final rule adopts a different approach for senior executives than for other workers. For senior executives, existing noncompetes can remain in force. Existing noncompetes with workers other than senior executives are not enforceable after the effective date of the final rule.
  - Fewer than 1% of workers are estimated to be senior executives under the final rule.
  - Specifically, the final rule defines the term "senior executive" to refer to workers earning more than $151,164 annually who are in a "policy-making position."

THANK YOU

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Different Approaches in the 50 States

1. At least 35 states that apply to physicians
2. Some of general application, e.g., CA, MN, etc.
3. Docs only: CO, CT, DE, IN, LA, MA, NH, RI, TX, WV.
4. Some to Docs and HCP: MD, NM, PA, SD, TN (x2).
5. No slowdown notwithstanding FTC Rule.
6. Trends: primary practice cite, causation, notification

FTC Non-Compete Rule

- 16 CFR Part 910; 89 Fed. Reg. 38342 (May 7, 2024)
- Prohibits entering into or enforcing non-compete clauses
  - Worker: e.g., employee, independent contractor, extern, intern, volunteer
  - Non-compete clause: term or condition that prohibits, penalizes, or prevents:
    - Work after conclusion of employment/relationship
    - Operating a business in U.S after conclusion of employment/relationship
- Requires written notice of unenforceability
- Scheduled effective date: September 4, 2024

FTC Non-Compete Rule (cont'd)

- Exceptions:
  - Sale of business or ownership interest
  - Pre September 4, 2024 restrictions on senior executives
    - Senior executive:
      - Policy-making position (including physician partners in a physician practice)
      - At least $151,164 per annum compensation
  - Tax-exempt nonprofit entities
  - Concurrent during employment

FTC Non-Compete Rule: Litigation

Case	Date	Holding	Rationale

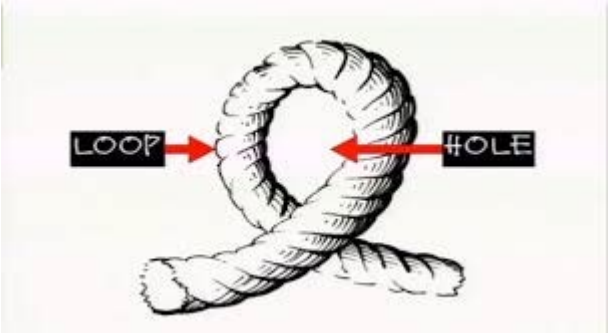
Ryan LLC v. FTC, 2024 WL 3879954 (N.D. Tex.)	8.20.24	Enjoin enforcement of the Rule (national)	• Rule exceeded FTC's authority
			  • FTC lacks substantive rulemaking authority on unfair competition
			• Arbitrary and capricious
			  • lack of evidence for the sweeping prohibition

Properties of the Villages, Inc. v. FTC, 2024 WL 3870380 (M.D. Fla.)	8.15.24	Enjoin enforcement of the Rule against plaintiff	• Substantial likelihood that the Rule exceeds FTC's authority, under major questions doctrine – no clear Congressional authorization • Judge said questions are "close"

ATS Tree Services, LLC v. FTC, 2024 WL 3511630 (E.D. PA)	7.23.24	Deny plaintiff's motion for preliminary injunction	• Plaintiff will not suffer irreparable harm from enforcement of the Rule
			• Plaintiff unlikely to succeed on merits
			  • Congress granted FTC substantive rulemaking authority to prevent unfair competition
			  • Major questions doctrine NA

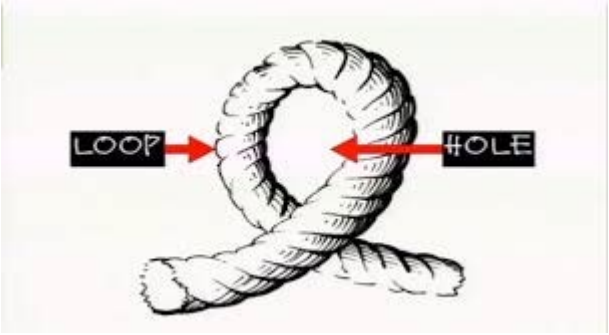
Non-Compete Alternatives

- Contract Entered Into Prior to September 4, 2024
- Exceptions (Rule Section 910.3)
  - Bona fide sales of:
    - a business entity
    - the person's ownership interest in a business entity
    - all or substantially all of a business entity's operating assets.
  - Causes of action accrued prior to September 4, 2024.
  - Good-faith basis to believe the Rule is inapplicable.



Non-Compete Alternatives

- Option to Purchase Goodwill of Departing Employee
- Require Resign Privileges at Hospital
- Proprietary Information
  - Patient lists
  - Advertising
  - Process Patents
- Non-Solicitation of Patients, Employees and Referral Sources
- Proactively Make Patient Assignments to Discourage Patient Loyalty
- Nondisparagement



Restrictive Covenant Strategies

Variables:

- Status of FTC Non-Compete Rule
- State law
- Circumstances
  - Negotiating leverage
  - Objectives
  - Plans
- consideration

Restrictive Covenant Strategies (cont'd)

Negotiation

- When does covenant apply?
  - During employment
  - Post-employment
  - Termination
    - Without cause by employer
    - For cause by employee
    - For cause by employer
    - Grounds for "cause" termination

Restrictive Covenant Strategies (cont'd)

- Scope
  - Restricted territory
    - From where?
  - Restrictive services – e.g., specialties, ancillary services
  - Nonsolicitation
    - What about employee's contacts, relatives, prior patients?
    - Social media
  - Permitted outside activities and investments
  - Time

Restrictive Covenant Strategies (cont'd)

- Consideration
- Buy-out right
- Cumulative remedies, including injunctive relief
- Blue pencil rule, severability
  - The Parties intend the terms, restrictions, covenant and promises contained herein to be binding only to the extent legal, valid and enforceable. If any term, restriction, covenant or promise contained herein is illegal, invalid or unenforceable, the Parties agree that such term, restriction, covenant or promise shall be modified (or deleted) as necessary to make it legal, valid and enforceable. In the event that a modification is not permitted, a provision found by the court or tribunal to be illegal, invalid or unenforceable shall be deemed severed and deleted, and the validity and enforceability of the remaining provisions shall not be adversely affected or impaired.
- Notices
  - Defend Trade Secrets Act public policy immunity notice - 18 U.S.C. § 1833(b)
  - Advice to consult an attorney

MARYLAND LEGISLATION BANNING NON-COMPETE CLAUSES FOR HEALTH WORKERS

GENE M. RANSOM, MEDCHI – THE MARYLAND STATE MEDICAL SOCIETY

MedChi
The Maryland State Medical Society

House Bill 1388: Labor and Employment:

Noncompete and Conflict of Interest Clauses for Veterinary and Health Care Professionals and Study of the Health Care Market (passed). MedChi adopted a Resolution in the fall of 2023 supporting the elimination of non-compete clauses in physician contracts and limiting their scope, the result of years of work by the Restrictive Covenant Task Force within MedChi.

As introduced by Delegate/Dr. Terri Hill, this bill prohibited such clauses and was retroactive. MedChi and other health care professions strongly supported the bill.

THE PROCESS ALTERED THE LEGISLATION

- The Maryland House of Delegates removed the retroactivity clause because of constitutional concerns (the US Constitution prohibits the impairment of existing contracts) but passed the bill overwhelmingly, despite the objections of MedStar and the Maryland Hospital Association.
- In the Senate, the same entities pushed for amendments that banned noncompete clauses for those earning compensation less than $300,000 per year, but allowed them above that threshold, so long as the clause did not exceed 1-year and a 10-mile radius. Their amendments also sought a study of the effect of private equity firms buying physician practices and to delay implementation of the bill until July of 2025.

MedChi worked with Senate Finance (FIN) Committee Chair Pamela Beidle to modify the proposed amendments. Through our modifications, the bill measures the 10-mile radius from the primary place of employment, increases the salary threshold to $350,000, and expands the study to include all types of acquisitions of physician practices, including by hospitals.

The importance of this legislation to physicians cannot be overstated. While we would have preferred the bill as adopted by the House, not taking what is still a significant improvement over the current law posed unknown risks and would have allowed the opposition to mobilize their considerable resources heading into 2025.

With this result, physicians earning less than $350,000 cannot be subject to non-compete clauses at all, and those above that amount are protected from terms that are geographically overbroad (for example, when a hospital system measures the distance from ANY of its facilities in the State) and longer than 1-year.

FTC ACTION – MOST LIKELY WON'T MATTER IN MARYLAND

- The following outline provides a high-level overview of the FTC's proposed final rule:
- The final rule bans new noncompetes with all workers, including senior executives after the effective date.
  - Specifically, the final rule provides that it is an unfair method of competition—and therefore a violation of Section 5 of the FTC Act—for employers to enter into noncompetes with workers after the effective date.
- For existing noncompetes, the final rule adopts a different approach for senior executives than for other workers. For senior executives, existing noncompetes can remain in force. Existing noncompetes with workers other than senior executives are not enforceable after the effective date of the final rule.
  - Fewer than 1% of workers are estimated to be senior executives under the final rule.
  - Specifically, the final rule defines the term "senior executive" to refer to workers earning more than $151,164 annually who are in a "policy-making position."

THANK YOU

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Structuring Remote Patient Monitoring Arrangements

ASMAC Fall Conference

October 28, 2023

Rick Hindmand

McDonald Hopkins LLC

rhindmand@mcdonaldhopkins.com

Agenda

- RPM and RTM Billing Standards
- Collaboration Structures
- Contracting Considerations
- Managing Compliance Concerns

Remote Patient Monitoring: Background

- Remote Physiologic Monitoring (RPM)
  - Collection and analysis of patient physiologic data to develop and manage a treatment plan for patients' chronic or acute conditions
  - Allow practitioners to remotely monitor patient conditions (e.g, temperature, pulmonary function, blood pressure) using digitally connected devices (e.g., sensors, pulse-oximeters, home blood pressure monitors)
- Remote Therapeutic Monitoring (RTM)
  - Monitoring of nonphysiologic health conditions (e.g., musculoskeletal or respiratory system status, therapy adherence, cognitive behavioral therapy)
  - Review and monitoring of therapeutic response signs, symptoms, functions.

Remote Patient Monitoring: Background (cont'd)

Process

- Device set up and education
- Collect and report data
- Analyze and interpret the remotely collected data
- Develop a treatment plan informed by the analysis and interpretation of the patient's data
- Practitioner manages the treatment plan until the targeted goals of the treatment plan are attained, ending the episode of care

Remote Patient Monitoring Codes

Remote patient monitoring – RPM and RTM similar codes:

- Initial setup and education (PE only code)
- Monthly supply and transmission of the medical device (PE)
- Monthly treatment management
  - 20 minutes/month
  - Add on 20 minutes/month
- Current Procedural Terminology (CPT®) is a registered trademark of the American Medical Association (AMA).

RPM/RTM Device Setup & Patient Education

Element	99453	99473	98975
Device & Services	RPM setup/education	Education, training, device calibration	RTM setup/education
Conditions monitored	Physiologic	Self-measured blood pressure	Non-physiologic
Billing Practitioner	Physician, NPP	Physician, NPP	QHP
Supervision	General	General	General
When	Once	Once	Once
Medical Device (FDA)	Yes	Validated for clinical accuracy	Yes
Require auto upload?	yes	No	No
Condition	Acute or chronic	-	-
National Allowable (Non-Facility)	$19.32	$12.88	$19.32

RPM/RTM Device Supply/Transmission

Element	99454	99474	98976	98977	98978
Device & Services	RPM supply/trans	Collection of readings, report and treatment plan	RTM supply/trans	RTM supply/trans	RTM Supply/trans
Conditions monitored	Physiologic	Blood pressure	Respiratory	MSK	Cognitive behavioral
Billing Practitioner	Physician, NPP	Physician, NPP	QHP	QHP	QHP
When	30 days (16 minimum)	30 days (12 reading min)	30 days (16 minimum)	30 days (16 minimum)	30 days (16 minimum)
Medical Device (FDA)	Yes	Validated	Yes	Yes	Yes
National Allowable (NF)	$50.15	$15.25	$50.15	$50.15	Contractor priced

RPM/RTM Professional Codes

Element	99457/99458	98980/98981	99091
Services Captured	RPM Treatment mgmt	RTM Treatment mgmt	Collection & interpretation of physiologic data
Conditions monitored	Physiologic	Nonphysiologic	Physiologic
Billing practitioner	Physician, NPP	QHP	Physician, NPP
Condition	Acute or chronic	-	-
Supervision	General	General	Direct
When	Calendar Month	Calendar month	30 days
Time Requirement	20/add'l 20 min	20/add'l 20 min	30 min
National Allowable (NF)	$48.80 / $39.65	$49.48 / $39.65	$54.22

External ECG Cardiovascular Monitoring CPT Codes

Element	93224-93227	93241-93244	93245-93248	93228-98229	93268, 93970-2
Monitor type	Holter	Long-term continuous	Long-term continuous	Mobile cardiac telemetry	Event
Surveillance	No	Yes	Yes	Yes	Yes
Automatic transmission	No	No	No	Yes	No
Services	Record/store; scanning analysis & report; review/interp	Record/connect; scanning analysis & report; review & interp	Record/connect; scanning analysis & report; review & interp	Review/interp; tech support, surveillance, analysis & report	Record/connect; transmission & analysis; review & interp
Time	Up to 48 hours	48+ hours-7 days	7+ to 15 days	Up to 30 days	Up to 30 days
Nat'l pay	$73.54 (global)	$267.37 (global)	$281.60 (global)	93228 :$25.42 93229:$849.55	$180.62 (global)

RPM/RTM Billing Principles

- Medical device
  - FDA definition of medical device (FDA clearance not necessarily required)
    - Intended for use in diagnosis, or in cure, mitigation, treatment or prevention of disease; or
    - Intended to affect the structure or function of the body other than chemically
  - Automatically upload data, and capable of generating/transmitting daily recording of data or an alert (RPM)
  - Collect & transmit reliable & valid data to develop & manage treatment plan
  - Reasonable and necessary

RPM/RTM Billing Principles (cont'd)

- Eligible patient
  - chronic or acute condition (for RPM)
  - established patient relationship
    - professional services from the physician/QHP or another physician/QHP of the exact same specialty and subspecialty who belongs to the same group practice, within the prior 3 years
    - Includes PHE patients

RPM/RTM Billing Principles (cont'd)

- Patient consent must be obtained
  - Need to document verbal consent in medical record or obtain in writing
  - During PHE patient consent can be obtained when RPM services are furnished (rather than requiring prior consent, as prior to the PHE)
  - During the PHE patient consent can be obtained by contracted staff
- Medical necessity for diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member
- Used to develop and manage a treatment plan
  - For a chronic or acute condition (for RPM)

RPM/RTM Billing Principles (cont'd)

- Interactive communication (99457/99458, 98980/9898)
  - real-time interaction with the patient or caregiver
  - real-time synchronous, two-way audio interaction that is capable of being enhanced with video or other kinds of data transmission
- Pay only one practitioner per code per patient

RPM/RTM Billing Principles (cont'd)

- Concurrent billing (RPM or RTM) allowed with some codes; e.g.:
  - Transitional care management
  - Chronic care management; principal care management
  - Behavioral health integration
  - Chronic pain management
- Limitations on concurrent billing
  - No double counting
  - Not on same day of E/M services
  - Concurrent billing not allowed for RPM and RTM

RPM/RTM Distinctions

- Nature of the data and how it is collected
  - RPM: physiologic; RTM can collect nonphysiologic
  - RTM codes: monitoring respiratory, musculoskeletal systems, cognitive behavioral and conditions
  - RTM can be self-reported or digitally reported; RPM data must be digitally (automatically) reported
- Code classification: RPM – evaluation and management (E/M) codes; RTM – general medicine codes
- RPM – chronic or acute conditions

RPM/RTM Distinctions (cont'd)

- Ordering, billing, supervising and performing professionals
  - RPM: must be ordered and supervised by physician or NPP
  - RTM: qualified healthcare professional - e.g., physician, NPP, therapist (OT, PT, SLP), clinical social worker, psychologist
  - CMS expected primary billers of RTM to be physiatrists, NPs and PTs
- RTM: "sometimes therapy" codes
  - Therapy plan of care required for devices specific to therapy services. RTM can be billed by a physician or NPP outside a therapy plan of care
- RTM – designated health services (subject to Stark Law)

RPM/RTM Distinctions: Supervision

- RPM services are designated care management services, and so can be furnished "incident to" services under general supervision
  - Auxiliary personnel 99457 and 99458
  - 99091 – direct supervision
- CMS recognized in MPFS 2023 Final Rule that RTM can be furnished under general supervision (direct supervision previously required)
- PT/OT can supervise a therapy assistant

FQHCs and RHCs

- Federally qualified health centers (FQHCs) and rural health centers (RHCs) are currently not allowed to bill for RPM/RTM
- Medicare Physician Fee Schedule (MPFS) 2024 proposed rule would allow FQHCs and RHCs to bill for RPM and RTM under HCPS Code G0511

Expired PHE Flexibilities

Restriction	PHE Flexibility
Established practitioner/patient relationship (3 years)	Allowed for new (in addition to established) patients; CMS: patients who received RPM, RTM or other communication technology-based services during PHE and consented are established patients
Face-to-face visit	Initiating visit can be by telehealth
Collection of copays/deductibles	Flexibility to waive/reduce cost sharing (per OIG)
16+ day monitoring/30 days (RPM)	2+ day monitoring for COVID-19/30 days
Stark Law in-office ancillary services exception (IOAS) location requirement	CMS blanket waiver of various Stark Law restrictions, e.g., IOAS location requirement

RPM/RTM Collaborative Business Models

- RPM/RTM ordered and billed by practitioner (reassign to employer)
- Medical device companies
  - Device development, customization and support
  - Supply devices
- Software/hardware/transmission platform – facilitate RPM/RTM
  - End user license agreement (EULA)
  - Connection to EHR
  - Complementary technologies (e.g., artificial intelligence)

RPM/RTM Collaborative Business Models (cont'd)

- Clinical staffing – care management services
- Supervising practitioner staffing
- Management and administrative services
- Support value-based payment and/or clinical integration
  - Clinically integrated networks, ACOs, payors
- Hybrid/ala carte

RPM/RTM Contracting and Collaboration

- Clinical Staffing Agreements
  - Ordering and supervision by billing practitioner
  - Avoid services furnished outside U.S. (42 CFR § 411.9)
    - U.S. ex rel. Cieszyski v Lifewatch Services, Inc. 2015 WL 6153937
  - No excluded individuals or entities
  - Service fees
  - Access to PHI and EHR
  - Data sharing
  - HIPAA Business Associate Agreement

RPM/RTM Contracting and Collaboration (cont'd)

- Satisfaction of CPT elements
- Documentation
- Corporate practice of medicine
- Fee-splitting
  - State law
  - Compensation to staffing company
  - Percentage of collections or billings

Fraud and Abuse

- Stark Law - 42 U.S.C. § 1395nn
  - Prohibits physicians from referring Medicare patients (and the entity from billing) for designated health services (DHS)
    - To an entity with which the referring physician (or immediate family member) has a direct or indirect financial relationship
    - Unless a Stark exception is satisfied
  - DHS includes RTM codes 98975-7, 98980-1
  - In-office ancillary services exception - 42 C.F.R. § 411.355(b)
    - Where is RTM service furnished? (42 C.F.R. § 411.355(b)(5))
    - Physician referral; physician supervision

Fraud and Abuse (cont'd)

- Federal Anti-Kickback Statute (AKS)
  - prohibits the knowing and willful offer, solicitation, payment or receipt of remuneration in return for or to induce any referral, purchase, lease or order of items or services under any federal health care program
  - Referral relationships
  - Contractual joint venture?
  - Safe harbors
- State self-referral and anti-kickback laws
- False Claims

Privacy and Security Safeguards and Breach Notification Requirements

- HIPAA Privacy, Security, and Breach Notification Rules
- FTC Privacy Policies and Security Requirements
- State Law Requirements, Particularly with regard to Sensitive Information
- Business Associates

Policies and Procedures

- Identification of eligible/appropriate patients
- Determine appropriate RPM/RTM, staff and treatment plans
- Patient consent
  - Acknowledge copay obligations
- Documentation in the medical record
- Coordination/communication among practitioner and staff

Policies and Procedures (cont'd)

- Practitioner supervision and review
- Recording and documentation of time
- Communications with patients
  - at least one interactive communication per month

Physician/NPP Responsibilities

- Eligibility to bill and supervise RPM/RTM
  - RPM: Physician/NPP
  - RTM: Physician/NPP/other qualified healthcare professionals (e.g., PT, OT, SLP)
- Ultimate responsibility for services billed and for patient care
- Develop (or review and approve) policies and procedures
- Approve the staff members and review/develop the training

Physician/NPP Responsibilities (cont'd)

- Professional judgment
  - Determine conditions to be monitored and parameters
  - Type of device
  - Threshold levels for readings
    - process for escalating the issue to the supervising physician/NPP
  - Regularly review findings and reports
  - Medical necessity
  - Use monitoring to manage care

Incident To Standards

Incident to requirements - 42 C.F.R. § 410.26(b) (e.g.)

- an integral, though incidental, part of the service of a physician or NPP in the course of diagnosis or treatment of an injury or illness
- General supervision
  - 42 C.F.R. § 410.32 (b)(3)(i):
    - furnished under the billing physician's/NPP's overall direction and control
    - physician's/NPP's presence is not required
    - Physician/NPP is responsible for training and maintenance of equipment and supplies

Documentation

- Physician/NPP order for the device or service
- Condition of the patient and medical necessity of the monitoring
  - Medical record
- Patient consent – medical record
- Device:
  - Medical device
  - Dates (e.g., delivery, service)
  - condition

Documentation (cont'd)

- Monitoring sufficient number of days
- Interactive communication
- Date of service
- Place of service

Counting and Documentation of Time

Counting time – 99457/99458, 99091, 98980/98981

- Aggregation of time
- No duplicate time
- No rounding up or carryover to get to the minimum
- No counting of time on a day when the billing practitioner reports an E/M service
- Document start and stop times on each date, identify the servicing person and services

Questions?

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Physician Unionization: Collective Bargaining from a Physician Perspective

Diomedes Tsitouras, AAUP-BHSNJ

What is Collective Bargaining?

“Collective bargaining is the process in which working people, through their unions, negotiate contracts with their employers to determine their terms of employment, including pay, benefits, hours, leave, job health and safety policies, ways to balance work and family, and more. Collective bargaining is a way to solve workplace problems. It is also the best means for raising wages in America. Indeed, through collective bargaining, working people in unions have higher wages, better benefits and safer workplaces.”

-AFL-CIO

Why should Physicians Engage in Collective Bargaining?

- Gives doctors a stronger voice and opportunity for communication in the healthcare workplace and beyond
- Shifts power back to the doctor, especially economic power
- Focuses on the needs of the doctor as an “employee”
- A possible antidote that can be used to counteract high burnout/moral injury
- Could help build membership

ABOUT AAUP-BHSNJ

The American Association of University Professors – Biomedical and Health Sciences of New Jersey (AAUP-BHSNJ) is an independent, non-profit organization that represents 1400 faculty at Rutgers/Rowan Universities. These faculty teach the next generation of doctors, nurses, scientists, and health professionals. The Association furthers the interests of faculty by bargaining for improvements in clinical compensation, researcher incentives, work/life balance, and other benefits. We also defend members from discriminatory treatment and provide individual advice on an array of issues. Finally, we advocate for our students, patients, and colleagues in Trenton by advancing legislation which promotes their interests.

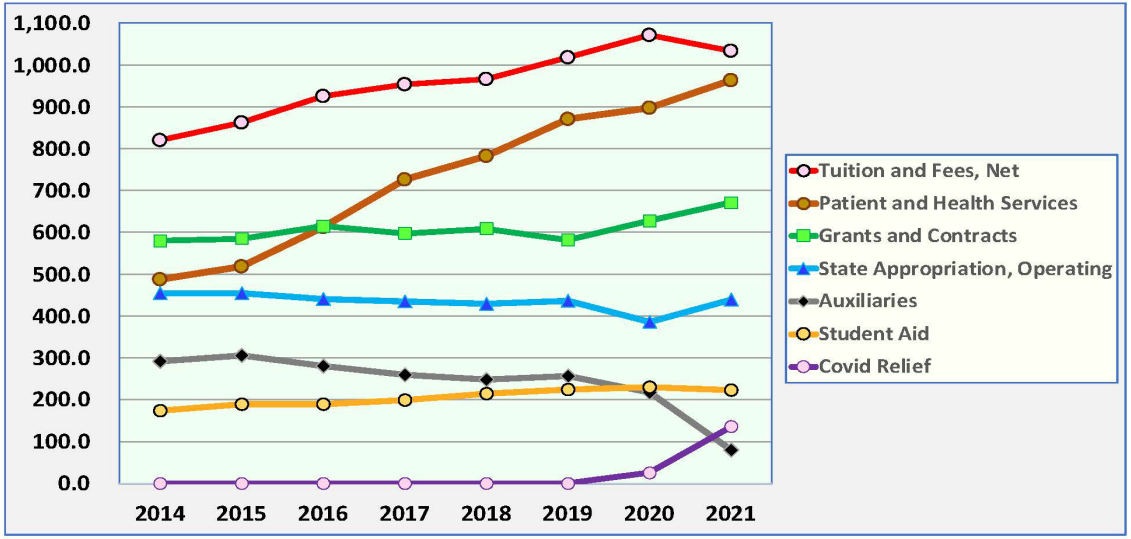
What has our Union (AAUP) Accomplished Through Collective Bargaining?

- **Improved minimum pay standards based on AAMC benchmarks.**
- **Bargained Better use of wRVU data tables (MGMA etc.).**
- **Created mechanisms to reduce gender-based and arbitrary pay inequity.**
- **Enhanced access to childcare, parental leave and other policies that support better work-life balance.**
- **Moved faculty to longer appointment periods with greater job security.**
- **Reduced the use of overly-broad restrictive covenants in appointment letters.**
- **Stopped increases to health insurance premiums.**
- **Strengthened health and safety protections.**

How much money do Universities receive from patient care?

Rutgers Main Revenue Over Time

Source: Audited Financial Statements



Current Issues AAUP-BHSNJ is Bargaining or Grieving

- The addition of a Fully Variable Supplement, an additional component of pay based on wRVU productivity
- Anesthesiology call pay
- Pathology clinical incentives
- Losses of pay associated with the Change Healthcare cyberattack
- Arbitrary pay inequity between members
- Purported overpayments made to members by the University

Doctors unionize as healthcare services are consolidated into corporate systems

– PBS Newshour January 1, 2024

Physicians and the National Labor Relations Act

- **Employed physicians who are not supervisors have the right under the NLRA, to self-organization, or form, join and assist labor organizations, to bargain collectively through representatives of the own choosing, or to engage in concerted activities**
- **No formal union required for certain NLRA protections**
- **Physicians-in-training**
- **Physicians Who Are Supervisors and Not Protected by the NLRA**
- **Self-Employed Physicians**

How are Unions Formed and Contracts Negotiated?

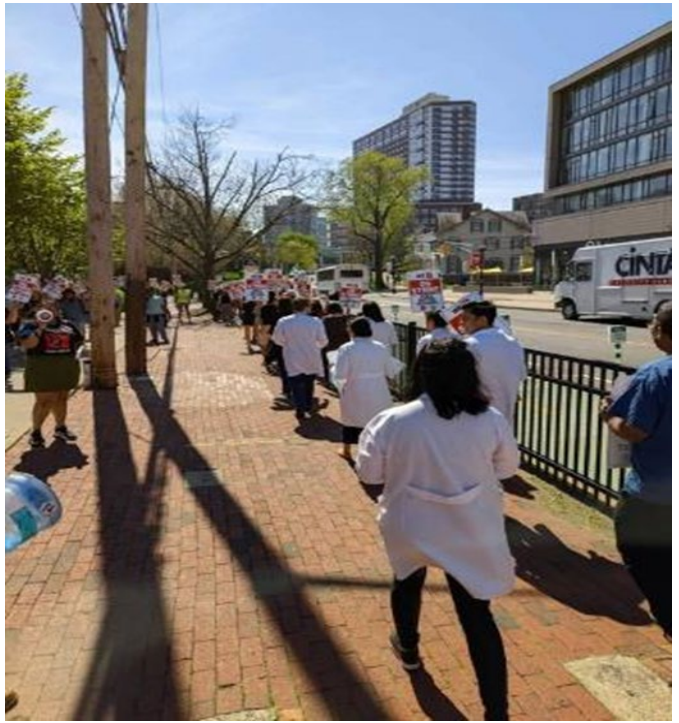
- **Card drive by which a majority of employees in a "unit" sign cards asking for a single entity to be their "exclusive representative" or voluntary recognition by the employer**
- **A "unit" can be any group of employees who are "logically placed together" for the purposes of collective bargaining.**
- **Where there is no voluntary recognition, the National Labor Relations Board (or comparable labor board) schedules an election where all "unit" members vote either in favor of creating the exclusive representative or against it.**
- **Assuming a favorable outcome for exclusive representative, such entity then bargains a contract with the employer covering bargainable terms and conditions of employment. Such entity is usually made up of certain employees of the unit who form a bargaining committee for the purposes of such negotiations.**
- **Once contract negotiated, typically such contracts will contain a grievance procedure by which terms can be enforced.**

Physician Unions (Collective Bargaining) as One Way to Combat Excessive wRVU Driven Expectations and Large Health System Power

- **Given that there are more employed physicians than in decades prior, physicians are increasingly using collective bargaining to protect their well being and to push back against risk-based-wRVU pay mechanisms.**
- **Antitrust challenges that existed in the 1990s may not exist today with big health systems/different economic landscape.**
- ***The Moral Crisis of America's Doctors* – "The corporatization of health care has changed the practice of medicine, causing many physicians to feel alienated from their work." *New York Times*, Eyal Press, June 15, 2023**
- **Addressing Private Equity and Related Expectations**

"Cardiology practices have become the latest fixation of private equity firms looking to profit from them. Ever since Medicare began paying doctors to perform common procedures in less expensive outpatient settings, financial investors have been racing to buy up cardiology practices. Experts fear that private equity's growing stronghold in the industry could exacerbate the overuse of cardiovascular procedures that are actually unnecessary for patient" -WBUR

Will Doctors Have to Go on Strike?



Rutgers unions picket as medical faculty remain frustrated at lack of contract progress (NorthJersey.com)

Will Doctors Have to Go on Strike?

- **No.**
- **Strikes are very *rare* among doctors and employees in general.**
- **There are multiple ways of exercising collective power or gaining leverage in a negotiation. Striking is only one of them.**
- **Your local union leadership will likely take a strike vote of members before striking. If such votes don't get at least 90% of members agreeing to strike, a strike is not likely.**
- **Patient safety is always taken into consideration. Actually, the law mandates notice to the employer before striking for this very reason.**
- **Sometimes a union contract or the law will prohibit striking.**
- **Some evidence that in the rare situations where healthcare workers do strike, patient health conditions and mortality actually improves.**

Are there Challenges Physicians Face in Forming Unions?

- **Yes.**
- **Employer may mount anti-union campaigns. (See Amazon, Starbucks)**
- **Sometimes labor relations law is old and weak.**
- **Occasionally forming a union or negotiating a contract may take time.**
- **Given poor union density, doctors lack familiarity with unions, how they work, and what they do**
- **Mythology around unions**
- **Dealing with special provisions physicians may already have within individual employment contracts**

***However*, education and empowerment is the first step for any physician using collective bargaining as a tool. The above challenges should not prevent those interested in forming unions from doing so.**

How can the AMA or Medical Societies Engage with Collective Bargaining and Support the Physician Employee?

- Nursing Associations as a model? Way to boost membership?
- Partnering with existing national unions which have expertise?
- Not all organizing drives need to be large.
- Short of organizing, the AMA and medical societies can foster norms and culture that supports employment rights and physician unions.
- Provide resources, know-your-rights trainings, and mutual-aid type services for doctors as employees.
- Support local efforts to organize healthcare workers when they occur.
- Use its influence and unique role with accrediting medical schools to foster employment rights within the medical school.
- Support federal and state legislation that enables physician collective bargaining and stronger employment rights which benefit physicians and other healthcare employees.

AMA
AMERICAN MEDICAL ASSOCIATION

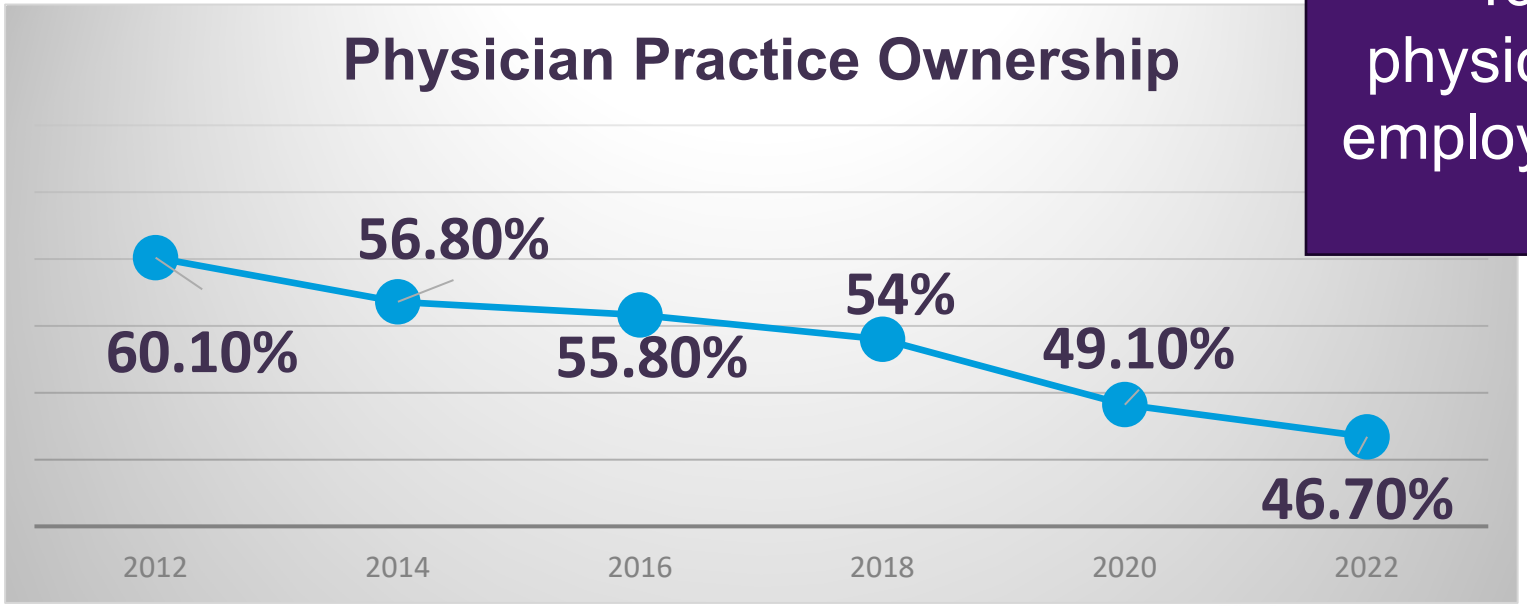
Physician Unions

ASMAC Fall Conference
October 2024

AMA policy on physician unions

- Supports the right of physicians to engage in collective bargaining
- Supports expanding the definition of “supervisor”
- Encourages physicians who engage in advocacy activities to avoid forming unions with workers who do not share physicians’ primary and overriding commitment to patients
- AMA Code of Ethics prohibits engaging in any strike that involves withholding essential medical services from patients

AMA Research: practice ownership is declining



49.7% of physicians were employed in 2022

Unionization Landscape

- AMA estimates that 11,000+ physicians and physicians in training joined unions in 2023 and 2024
- **Skyrocketing among residents**
  - Committee of Interns and Residents (CIR) represents 20% of medical residents
  - Up from 10% in 2019
- **Growing among employed physicians**
  - 6.3% of physicians, 7.1% of surgeons union members in 2023
  - Up from 5.7% in 2014
  - More are covered under union contracts

Unionization Landscape

Residents and Fellows	Employed Physicians
Northwestern University	Allina - Minnesota & Wisconsin
Mass General Brigham - Boston	Salem Hospital (Mass General Brigham)
University of Pennsylvania	Cedars-Sinai Anesthesiologists
Montefiore Medical Center	Southern Oregon – ED Physicians
Stanford Health Care	
University of Southern California - Keck	
UChicago	

Unionization Landscape

- Residents have been successful in negotiations around wage increases, health insurance, retirement contributions, parental leave, and work hours.
  - Ripple effect to non-union institutions: E.g., 8-week parental leave
- Employed physicians cite staffing levels as a primary driver of unionization
  - Note nursing unions in the news as systems can't meet the staffing ratios to which they agreed
- Research of all healthcare unions suggests that unionized healthcare workers have higher weekly earnings and better noncash benefits (e.g., pension and employer-paid full-premium health plan), but higher weekly work hours—for physicians, no significant difference.

“Supervisor” status

- ***Piedmont Health Services Medical Providers United (2022)****, 10-RC-286648, Decision and Direction of Election (DDE):* physicians are not supervisors under the NLRA simply by virtue of their position in the healthcare institution. physicians will not automatically be considered supervisors under the NLRA.

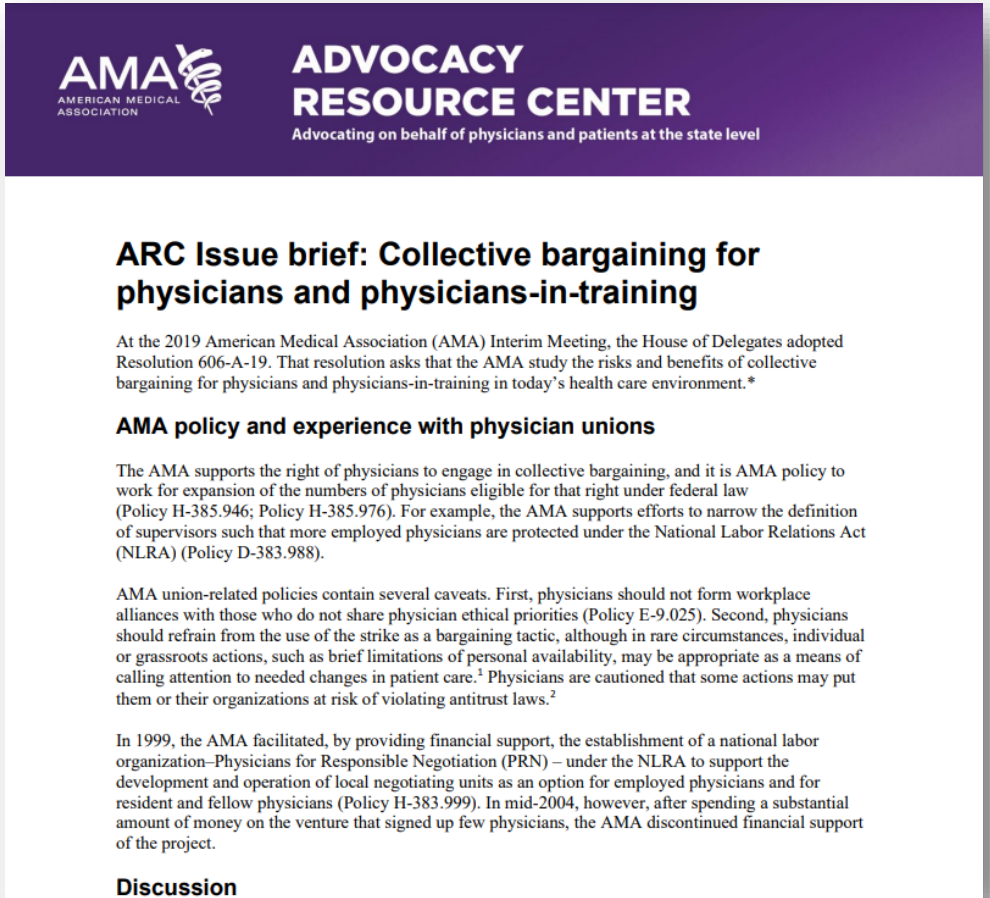
- ***ALLINA HEALTH D/B/A MERCY— UNITY CAMPUS (2023)****, 18-RC-312132*: a Chief of Staff and member of the Medical Executive Committee was not a supervisor, in part because she did not make final decisions on the hiring process and did not have the authority to impose discipline.
    - NLRA “requires … evidence of actual supervisory authority visibly translated into tangible examples demonstrating the existence of such authority.”
    - “The evidence must be detailed and specific, particularly with respect to the factors weighed or balanced in exercising putative supervisory authority, in order to establish independent judgment.”

Outstanding considerations

- What is the scope of negotiations – can unionization help physicians address the moral injury?
    - E.g., physicians often express interest in negotiating terms of insurance contracts
- Are there conflict of interest concerns where unions include non-physicians (e.g., NPs/PAs)?
- What leverage and bargaining power to avoid interruptions in patient care? (AMA CEJA is researching)
- What is the role of the medical society?

AMA Advocacy Issue Brief – Physician Unions

Find AMA's Advocacy Issue Brief on Collective Bargaining here: https://www.ama-assn.org/system/files/advocacy-issue-brief-physician-unions.pdf



AMA AMERICAN MEDICAL ASSOCIATION

ADVOCACY RESOURCE CENTER

Advocating on behalf of physicians and patients at the state level

ARC Issue brief: Collective bargaining for physicians and physicians-in-training

At the 2019 American Medical Association (AMA) Interim Meeting, the House of Delegates adopted Resolution 606-A-19. That resolution asks that the AMA study the risks and benefits of collective bargaining for physicians and physicians-in-training in today's health care environment.*

AMA policy and experience with physician unions

The AMA supports the right of physicians to engage in collective bargaining, and it is AMA policy to work for expansion of the numbers of physicians eligible for that right under federal law (Policy H-385.946; Policy H-385.976). For example, the AMA supports efforts to narrow the definition of supervisors such that more employed physicians are protected under the National Labor Relations Act (NLRA) (Policy D-383.988).

AMA union-related policies contain several caveats. First, physicians should not form workplace alliances with those who do not share physician ethical priorities (Policy E-9.025). Second, physicians should refrain from the use of the strike as a bargaining tactic, although in rare circumstances, individual or grassroots actions, such as brief limitations of personal availability, may be appropriate as a means of calling attention to needed changes in patient care.[1] Physicians are cautioned that some actions may put them or their organizations at risk of violating antitrust laws.[2]

In 1999, the AMA facilitated, by providing financial support, the establishment of a national labor organization–Physicians for Responsible Negotiation (PRN) – under the NLRA to support the development and operation of local negotiating units as an option for employed physicians and for resident and fellow physicians (Policy H-383.999). In mid-2004, however, after spending a substantial amount of money on the venture that signed up few physicians, the AMA discontinued financial support of the project.

Discussion

Physicians' powerful ally in patient care

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Discussion

The status of physician unions

The number of physicians who are members of unions is small in comparison to the size of the profession. Their numbers, however, are growing. In 1998, the AMA estimated that between 14,000 and 20,000 physicians were union members. In 2014, it appears that this number had grown to 46,689 (5.7 percent of 820,152 actively practicing physicians in the United States).[3] In 2019, there were 67,673 physician union members. This represents 7.2 percent of the 938,156 physicians actively practicing in the United States – a roughly 26 percent increase from 2014 in the percentage of physicians belonging to unions.[4]

**The information and guidance provided in this document are not intended as, and should not be construed to be, legal or consulting advice. Physicians should seek legal advice regarding any legal questions.*

Physicians have been successful organizing with the help of certain international unions, including the American Federation of State, County, and Municipal Employees (AFSCME), the Service Employees International Union (SEIU), and the American Association of University Professors (AAUP). AFSCME and SEIU have been successful in affiliating with existing physician unions, while the AAUP has been successful in tapping into academic physician interest in pursuing unionization.

The Union of American Physicians and Dentists, affiliated with AFSCME, is perhaps the largest physician union representing practicing physicians working for the State of California, California counties, non-profit health care clinics, and in private practice. The Federation of Physicians and Dentists, another AFSCME affiliate, is also a union with a history of organizing self-employed physicians in independent practice and challenging established labor and antitrust laws.

SEIU, the largest and fastest growing health care workers union in North America, with over 2.1 million members, is affiliated with the Doctors Council that began representing a group of physicians employed by the Departments of Health and Welfare of the City of New York. Today it negotiates for all attending physicians employed by New York City and the Health and Hospitals Corporation, the public safety net health care system of New York City. Doctors Council has expanded from New York to Illinois, New Jersey and Pennsylvania, where it represents physicians employed by academic medical schools, hospitals, professional corporations, and national corporations. SEIU is also affiliated with the Committee of Interns and Residents (CIR), the oldest and largest house staff union in the country representing more than 22,000 interns, residents, and fellows in California, Florida, Massachusetts, New Jersey, New Mexico, New York, and Washington, D.C.

The AAUP develops and disseminates information and resources in support of the collective bargaining activities of local chapters, including those comprised of academic physicians employed by academic medical centers and clinics. For that purpose, AAUP has established a separate 501(c)(5) organization that provides its services through AAUP staff and through consultants and others with specialized expertise.

The employment status of physicians

The large number of physicians now working as employees has by some reports re-energized the movement for physician collective bargaining.[5]

According to AMA's Physician Practice Benchmark Survey utilizing 2022 data, 49.7 percent of physicians are now employees.[6] Among employed physicians, 16.9 percent are employed directly by hospitals, 3.4 percent are employed by medical schools, and 6.3 percent are employed by faculty practice plans. Moreover, 13.8 percent of employed physicians work in practices that are wholly owned by other physicians.[7]

Younger physicians are more than twice as likely as older physicians to be employed by hospitals. In fact, 16.4 percent of the under 40 cohort are direct hospital employees compared to only 5.7 percent of physicians over the age of 54.[8]

The basic rights of employed physicians to engage in protected collective bargaining

Employed physicians – who are not supervisors – have the right under the NLRA and other applicable

labor laws, to self-organization, to form, join, or assist labor organizations; to bargain collectively through representatives of their own choosing; and to engage in other concerted activities for the purpose of collective bargaining or other mutual aid or protection. An employer and a union have a legal duty to negotiate any subject that relates to wages, hours and other terms and conditions of employment.

No traditional formal union required for NLRA protections

Physicians are not required to belong to a traditional formal union certified by the National Labor Relations Board (NLRB) to receive the NLRA's protection for employees engaged in concerted activities. Two or more employed physicians have the right to designate a representative and ask their employer to meet with the designated representative and to discuss and negotiate wages and other terms and conditions of their employment. Thus, in *New York Univ. Med. Ctr.*, 324 NLRB 887 (1997), the NLRB decided that the Association of Staff Psychiatrists (the Association), formed by staff psychiatrists at Bellevue Psychiatric Hospital, was a labor organization protected under the NLRA even though it was not a formal union. The NLRB reasoned that the Association was formed for the purpose of dealing with the hospital on such matters as salaries, working hours and conditions, and grievances of its members; had elected officials and dues paying membership; held membership meetings; and had dealt with the hospital through the director of psychiatry. Accordingly, the NLRB ruled that the hospital had violated the NLRA by impliedly threatening its employed physicians with cutbacks, layoffs, and other consequences if they continued to engage in the concerted conduct of protesting the discontinuance of certain Bellevue Hospital physician employment policies.

Physicians-in-training

Residents have organized out of a need to, "create a better and more just healthcare system for patients and healthcare workers and to improve training and quality of life for resident physicians, fellows and their families."[9]

Residents exercise and enjoy collective bargaining rights under the NLRA. Initially the NLRB treated residents as students unable to collectively bargain with the protections of the NLRA. That changed in 1999 when the NLRB held that house staff members are statutory employees with a right to organize under the NLRA. Scholars worried that an ensuing NLRB holding that graduate students had no right to bargain collectively would also apply to house staff. The NLRB, however, has reaffirmed house staff rights to bargain collectively.

Physicians who are supervisors are not protected by the NLRA

Individuals who fit the statutory definition of a supervisor are *not* protected by the National Labor Relations Act. The NLRA defines "supervisor" as:

> Any individual having the authority, in the interest of the employer, to hire, transfer, suspend, lay off, recall, promote, discharge, assign, reward, or discipline other employees, or responsibility to direct them, or to adjust their grievances, or effectively to recommend such an action, if in connection with the foregoing the exercise of such authority is not of a merely routine or clerical nature, but requires the use of independent judgment. [10]

Thus, the Supreme Court ruled in *NLRB v. Kentucky River Community Care Inc.,* 532 US 706 (2001), that certain supervising nurses at private hospitals could not join unions because they were "supervisors" as defined by the NLRA.

Although *Kentucky River Community Care* appears to be restrictive in terms of the pool of physicians who would qualify for union membership and the protections of the NLRA, it is not clear that the case has had that impact. Specifically, the NLRB has narrowed the meaning of "effectively to recommend" to be that the supervisor's recommended action is taken with *no* independent investigation by superiors. *Family Healthcare Inc. and Christine McCallum*, 354 NLRB No 29. (2009). Also, the NLRB has reasoned that to be deemed a statutory supervisor, the employee must be held by the employer to be accountable for the performance of other employees. *Oakwood Healthcare, Inc*, 348 NLRB No. 37 (2006). In light of these requirements for supervisor status, the NLRB has decided that a physician employed by a physician practice group was not a supervisor of nurse employees. *Family Healthcare Inc. and Christine McCallum*, 354 NLRB No 29. (2009). The physician's employment contract provided that she was to participate in the supervision of nurses; and she often provided evaluative comments on nursing staff to the practice's staff director; selected her own primary nurse from among candidates presented by the director; and complained about nurse performance issues to the director. The NLRB held, however, that it was the director and not the employed physician who made the final decisions about performance, termination, and compensation. [11]

Physicians wishing to avoid supervisory status are advantaged by a rule that places the burden to prove supervisory authority on the party asserting it. Also, the NLRB has generally exercised caution not to construe supervisory status too broadly. the NLRB, however, has indicated that physicians who are medical directors or have significant managerial responsibility are likely to be deemed "supervisors."[12]

As significant case law has developed surrounding the definition of "supervisors," physicians should consult with an attorney to determine whether they have the status of a supervisor.

Physicians are also cautioned to consider the professional ramifications of resisting the status of "supervisor." The AMA supports the use of physician-led team-based care, with care provided by members of the team providing care commensurate with their education and training. Physicians need to ask the question of whether they can be deemed nonsupervisory for purposes of the NLRA and still maintain their positions as the leaders of team-based care.

Academic physicians

Of the unionized academic physicians, most are in public institutions in states that authorize public employees to bargain collectively. That is because a U.S. Supreme Court case, *NLRB v. Yeshiva University*, 444 U.S. 672 (1980), concluded that tenured faculty at Yeshiva were "managerial employees" and thus excluded from the coverage of the NLRA. This seemingly confined physician faculty collective bargaining to the public sector where state collective bargaining law does not necessarily always follow NLRB precedent. A subsequent NLRB decision, however, suggests that many non-tenured faculty members at private institutions do not have enough power to be considered managerial.[13] This could clear the way for much more unionization under the NLRA of faculty members in private settings, including those who are physicians.

Self-employed physicians

To level the playing field with monopoly health insurers, self-employed physicians have looked for legitimate ways to collectively bargain with health plans without running afoul of the antitrust ban on price fixing. Some have formed a financially or clinically integrated network – a physician joint venture – that is essentially treated like a single firm that is incapable of forming a price-fixing conspiracy and free to negotiate with health plans. Others have lobbied for state or federal legislation that would grant immunity to independent physicians jointly negotiating with insurers.

In the 1990s, some physicians in independent practice hoped that by gaining recognition as a formal union, they could engage in collective bargaining with health plans under the labor exemption from the antitrust laws. Before physicians can engage in collective bargaining under the labor exemption, however, the bargaining process must be part of a labor dispute. For there to be a labor dispute, the collective bargaining must concern the terms and conditions of employment. The physicians, therefore, must be employees. There is no labor dispute for purposes of the labor exemption if the physicians are independent contractors, entrepreneurs, or independent businesses.

While courts are willing to look at the substance of the relationship to determine whether a person is an employee for purposes of the antitrust and labor laws, the concept of an employee is largely restricted to a common-law agency test that differentiates employees from independent contractors. To date, physicians have been unsuccessful in establishing that their contractual relationships with health insurers meet the control test for the NLRA rights afforded employees. Thus, *in AmeriHealth Inc./Amerihealth HMO*, 329 NLRB 76, 4-RC-19260 (1999), the NLRB decided that a group of in-network physicians were independent contractors, reasoning that the HMO did not regulate the patient-physician relationship in a manner comparable to that of an employer. The NLRB determined that the physicians had a "meaningful opportunity" to negotiate the terms of compensation with a health plan. The NLRB expressly held, however, that it was, "not necessarily precluding a finding that physicians under contract to health maintenance organizations may, in other circumstances, be found to be statutory employees."

More recently, the NLRB signaled a small shift in its definition of "independent contractor." Specifically, in 2011, the NLRB held that a group of symphony orchestra musicians were statutory employees, not independent contractors.[14] The decision largely hinged on the orchestra's right to control the manner and means by which the performances of professional musicians were accomplished. This paradigm could reasonably be applied to physicians. In recent years, the emergence of narrow networks, accountable care organizations, and other organizational forms of provider organizations have gained substantial control over the means by which physician services are performed. That development, together with the loss of a "meaningful opportunity" to negotiate compensation (the employee test in *AmeriHealth*), may be opening the door to the availability of NLRA coverage and of the labor exemption from the antitrust laws to an increasing number of physicians.

Bargaining units composed entirely of physicians are presumed appropriate

Like other employees, employed physicians can be in a formal bargaining unit certified by the NLRB. Hospital physicians have been successful in being recognized by the NLRB as an appropriate bargaining unit. Indeed, in 1989 the NLRB promulgated regulations in creating a presumption that in acute care hospitals a separate bargaining unit for physicians (e.g., one that excludes nurses and other types of employees) is appropriate.[15]

The advantages and disadvantages of physician unions

The dominant hospital and the case for physician countervailing power

As many physicians have recognized, independently bargaining a second or third contract with a hospital can be a difficult experience. Many hospital markets are highly concentrated and are becoming more so.[16] In a highly concentrated hospital market, a hospital-employed physician may have few hospital employment alternatives. Moreover, covenants-not-to-compete often exist in a physician's hospital employment contract, and these covenants may further contribute to a bargaining advantage that a hospital employer with market power may possess.

Dominant hospital employers may be under little, if any, competitive pressure to respond to an employed physician's request to renegotiate an equitable agreement that might offer competitive wages and benefits. Nor are hospitals with market power under competitive compulsion to respond to physician practice concerns in the areas of physical plant and equipment, support staff, and other resources it makes available to patients and physicians.

Physicians become upset when they feel that they have no influence or control over key decisions that affect them and their patients or that undermine their autonomy.[17] Additionally, there is the concern that physicians working for dominant hospitals could experience divided loyalties and may feel that the interests of the hospital may not always be consistent with what they believe is in the best interests of the patient.[18] Thus a combination of market conditions and the special organizational behavior needs of physicians may make the countervailing power that can be obtained through collective bargaining seem especially attractive to physicians who are employed by dominant hospitals. This creates a special opportunity for physician unions in the hospital setting.

Need for addressing the physician burnout epidemic

A major driver of physician unionization is physician burnout. Physicians face a burnout epidemic.[19] Physicians vigorously complain that they spend more time than ever on electronic health record (EHR) documentation and bureaucratic administrivia.[20] According to a Brookings report, for every hour a primary care physician spends in direct patient care, they spend two hours engaged in administrative functions.[21] Writing in the *New Yorker*, Eric Topol, MD, observes:

> Doctors now face a burnout epidemic: 35% of them show signs of high depersonalization, a type of emotional withdrawal that makes personal connections with their patients difficult. Administrative tasks have become so burdensome that according to one recent report, only 13% of the physicians' day, on average is spent on doctor-patient interaction. Another careful study of doctors' time is shown that, during an average 11-hour workday, six hours are spent at the keyboard, maintaining electronic health records.[22]

While many of the administrative burdens and sources of burnout are imposed by health insurers and government regulators and thus, outside the control of organizations employing physicians, physician collective bargaining with employers can certainly result in some relief. After all, one of the major reasons why many physicians have given up independence in exchange for health system employment is to enjoy an ever-larger army of clerical, administrative, and billing staff to help with the onerous requirements for getting paid.[23]

Possible loss of physician autonomy and of rewards for individual accomplishments

Detractors of physician unions point out that collective bargaining usually results in an agreement that applies uniformly to all physicians who participate in the collective bargaining. In particular, the level of compensation may be stratified based on seniority or obtainment of certifications, and it may be difficult to write contractual language that differentiates and addresses a significant divergence among physicians in terms of experiences and skills. Proponents of physician unions respond by asserting that their contracts are analogous to those negotiated by the Major League Baseball Players Association, which of course rewards a player's value to the team.

Physician strikes

Physicians regard their responsibility to the patient as paramount. Some physicians may fear that by joining a union they risk harming patients if collective action is taken. There are at least three responses to

this concern. First, physicians in a union need not resort to a strike in order to exercise power in the course of a contract negotiation. As one observer has noted, "[p]hysicians have other means of adjusting their workflow to affect their employer without rejecting all clinical duties. Examples of such adjustments include refusing to perform elective surgeries or neglecting documentation to prevent effective billing."[24]

Second and most significantly, there have been very few physician strikes, with most strikes occurring by physicians-in-training. The experience with physician unions going out on strike is that patients have not been harmed. Indeed, one study found that a physician strike by Los Angeles County physicians "was responsible for more deaths *prevented* than lives lost."[25]

Finally, the labor laws have been specifically designed to provide healthcare workers, including physicians, with a right to strike that is well tailored to protecting patients. When Congress enacted the 1974 amendments to the NLRA, extending coverage to nonprofit hospitals, it added a new Section 8(g), which requires unions to give ten-day notice before engaging in any strike or other concerted refusal to work at any health care institution. Section 8(g) was added because, in extending the protections of the NLRA to hospital employees, Congress meant to protect the public against undue disruptions in health care services resulting from labor disputes.[26] As the Senate committee's report on the measure stated:

> In the Committee's deliberations on this measure, it was recognized that the needs of patients in health care institutions required special consideration in the Act including a provision requiring hospitals to have sufficient notice of any strike or picketing to allow for appropriate arrangements to be made for the continuance of patient care in the event of a work stoppage.[27]

In short, "Congress chose to treat the health care industry uniquely because of its importance to human life."[28] Accordingly, the labor laws have been well-tailored to address physician ethical concerns.

Union formation by medical societies

Some medical societies may wish to consider whether the time has come to organize employed physicians and to provide collective bargaining for them. While it should be possible for a medical society to qualify as a labor organization, various conflicts could arise. Further work is needed by both the AMA and medical societies to determine the exact model necessary to execute successful organizing strategies.

Conclusion

The AMA's policies supporting a physician's right to unionize are being achieved. Thus, consistent with existing AMA policy, employed physicians may have the protections of labor law and enjoy an exemption from the antitrust laws when they engage in concerted action concerning the terms and conditions of their employment. Moreover, AMA policy supporting efforts to narrow the definition of supervisors (such that more employed physicians are protected under the NLRA) has received a boost from an NLRB decision finding that a physician was not a supervisor, a case that was decided subsequent to AMA's discontinuance of its financial support of PRN. Moreover, the NLRB has shown the tendency not to construe supervisory status too broadly and has recently classified certain faculty as nonsupervisory, setting the stage for the unionization of greater numbers of academic physicians. Finally, NLRB regulations create a presumption that it is appropriate for physicians in an acute care hospital to form a separate bargaining unit. This rule is consistent with the caveat contained in AMA policy that physicians should not form workplace alliances with those who do not share physician ethical priorities.

Although the unionized portion of the physician profession remains very small, in the many and growing

number of markets where hospitals have market power and where physicians have few hospital employment alternatives, there is arguably created the need for physician countervailing bargaining power.

A major driver of physician unionization is the physician burnout epidemic. Physicians vigorously complain that they spend more time than ever on EHR documentation and bureaucratic administrivia. Under these conditions, physician unions present a plausible opportunity to improve physician working conditions in ways that benefit both physician and patients. Unions may also achieve collective bargaining agreements that safeguard the shared interests of employed physicians wanting more control over their practices while also rewarding individual achievement similar to collective bargaining agreements in professional sports.

While physician collective bargaining with hospitals carries the risk of impasse and of a strike, the history of physician unions shows very few physician strikes. Patients are protected by a NLRA requirement that a hospital be given ten-day notice of any strike or picketing to allow for appropriate arrangements to be made for the continuance of patient care in the event of a work stoppage.

Finally, physicians and their medical associations should be aware that unions are highly regulated and present legal issues requiring the assistance of legal counsel familiar with the highly specialized area of labor law and the number of unique legal issues arising in health care, such as whether physicians are supervisors. In making arguments that they are nonsupervisory for the purpose of gaining NLRA protections, physicians should be cautious of undermining their positions as the leaders of team-based care.**

For more information on the issues raised in this issue brief, contact Henry Allen, JD, MPA, Senior Attorney, AMA Advocacy Resource Center, at henry.allen@ama-assn.org.

***This issue brief was prepared by AMA Advocacy Resource Center staff.*
The staff wishes to thank Diomedes Tsitouras JD, MPA for helpful comments.

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[1] Section 8(g) of the National Labor Relations Act prohibits a labor organization from engaging in a strike, picketing, or other concerted refusal to work at any health care institution without first giving at least 10 days' notice in writing to the institution and the Federal Mediation and Conciliation Service.
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. In addition to the 49.7 % of physicians who are employees, another 6.4% are independent contractors. The rest (44.0%) are owners.
[7] Unpublished estimates based on data from the AMA's 2022 Physician Practice Benchmark Survey.
[8] *Id.*
[9] See the Mission Statement of the Committee of Interns and Residents, which is affiliated with the Service Employees International Union. The mission statement may be accessed at http://www.cirseiu.org/who-we-are/
[10] 29 U.S.C. § 152(11),
[11] Family Healthcare Inc, 354 NLRB 254, 09-CA-044539 (2009).
[12] See, Thomas-Davis Med. Ctr. v. Fed'n of Physicians and Dentists, Case 28-RC-5449, N.LR.B. Region 28 (1996). The physician bargaining unit encompassed "all regular full-time and part-time physicians, including department chairs… excluding all other employees, physician medical directors, assistant medical directors…"
[13] Pacific Lutheran University and Service Employees International Union, 361 NLRB 157, 19-RC-102521 (2014).
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[20] Id. See also *See* Gaynor, Mostashari and Ginsberg, "*Making Healthcare Markets Work: Competition Policy for Health* Care", Carnegie Mellon University/Center for Health Policy, Brookings/USC Schaeffer Center for Health Policy and Economics (April, 2017) (" Brookings Report") at 12-15, available at: https://www.brookings.edu/research/making-health-care-markets-work-competition-policy-for-health-care/?utm_campaign=Economic%20Studies&utm_source=hs_email&utm_medium=email&utm_content=50778822
[21] Id at 13
[22] Eric Topal, M.D. ," Why Doctors Should Organize", the New Yorker (August 5, 2019) available at https://www.newyorker.com/culture/annals-of-inquiry/why-doctors-should-organize
[23] Brookings Report at 13.

[24] Danielle Howard, MD, "What Should Physicians Consider Prior to Unionizing" AMA Journal of Ethics, March 2020.
[25] *Id*
[26] *Hospital & Health Care Employees District 1199 (United Hospitals of Newark)*, 232 NLRB 443, 444 (1977); *Plumbers Local 630 (Lein-Steenberg)*, 219 NLRB 837, 838-839 (1975), enf. denied on other grounds 567 F.2d 1006 (D.C. Cir. 1977), overruled on other grounds 246 NLRB 970 (1979).
[27] S. Rept. 93-766, 93d Cong., 2d Sess. (1974
[28] *Hospital & Health Care Employees District 1199 (United Hospitals of Newark)*, 232 NLRB at 444.

CALIFORNIA MEDICAL ASSOCIATION

MICRA Modernization

(AB 35 - 2022)

October 2024

CMA

Brief Overview

Integrated Mechanisms

Original Statutory Provisions of MICRA, as Enacted in 1975

1. Advance Notice of a Claim
2. Statute of Limitations
3. Binding Arbitration of Disputes
4. Evidence of Collateral Source Payments
5. Periodic Payments of Future Damages
6. $250,000 Limit on Recovery of Non-Economic Damages
7. Tiered Attorney Contingency Fee Structure (1975: 26% / 1987: 29%)

(Punitive Damages Statute added in 1987)

2022 Ballot Initiative

2022 Threat To Decimate MICRA

Initiative invented a new category of injuries not recognized under California law:

- "catastrophic injuries:" "any level of permanent physical impairment, disfigurement, disability, or loss of consortium"

Requires Jury Be Told About Power To Make Finding Of Catastrophic Injury & Elimination of Caps

- If "catastrophic injury" is found:
  - MICRA's non-economic damages cap does not apply
  - MICRA's attorneys' fees structure does not apply

Requires Prevailing Plaintiff's Attorneys' Fees To Be Paid By Defendant

- If "catastrophic injury" found:
  - mandatory award of attorneys' fees to prevailing plaintiff paid by defendant on top of award

For Non-Catastrophic Injury Cases: Noneconomic Damages Cap & Attorney Fee Structure Adjusted to 1975 /1987

2022 Threat to Decimate MICRA

Eliminates Collateral Source Rule

- Allows for double-recovery by excluding evidence that a plaintiff's damages are compensated by another source

Eliminates Periodic Payments

- Eliminates the option of providing financial resources to an injured patient over time as their treatment and recovery continue

Extends Statute of Limitations

- Doubles primary statute of limitations from 1 year to 2 years
- Extends statute of limitations period for minors from 3 years to 4 years

Established False Pretense of Merit

Future Amendments

- Requires 2/3 vote of Legislature
- For amendments that are "consistent with and further the intent of this Act"

Application

- Applies to all cases pending as of 5 days after election results are certified

2022 Negotiations →
AB 35 – MICRA Modernization

AB 35 Modernizes and Updates MICRA

- AB 35 was a result of an agreement reached between Californians Allied for Patient Protection (CAPP) and the plaintiffs' attorneys
- AB 35 extends the long-term predictability and affordability of medical liability insurance premiums
+ Modernized framework will keep **MICRA's essential guardrails** solidly in place for patients and providers alike.

CMA

Who Made the Agreement?

- Californians Allied for Patient Protection (CAPP), the large and diverse coalition working to protect MICRA, approved the agreement.
  - California Medical Association
  - California Hospital Association
  - California Dental Association
  - Medical malpractice insurance carriers
  - Community clinics
  - Planned Parenthood Affiliates of California and MANY more.

Maintains Important Protections of MICRA

- Under AB 35, important guardrails of MICRA have been maintained:
  - Option for binding arbitration
  - 90-day advance notice of claim
  - One-year statute of limitations
  - Allowing other sources of compensation to be considered in award determinations (collateral source rule)
  - Limits on plaintiff's attorney's contingency fees – NEW STRUCTURE – 25% pre-filing; 33% post-filing
  - Periodic payments – NEW THRESHOLD - $250k

New Protections

Allowing Expressions of Sympathy, Apologies and Statements of Fault

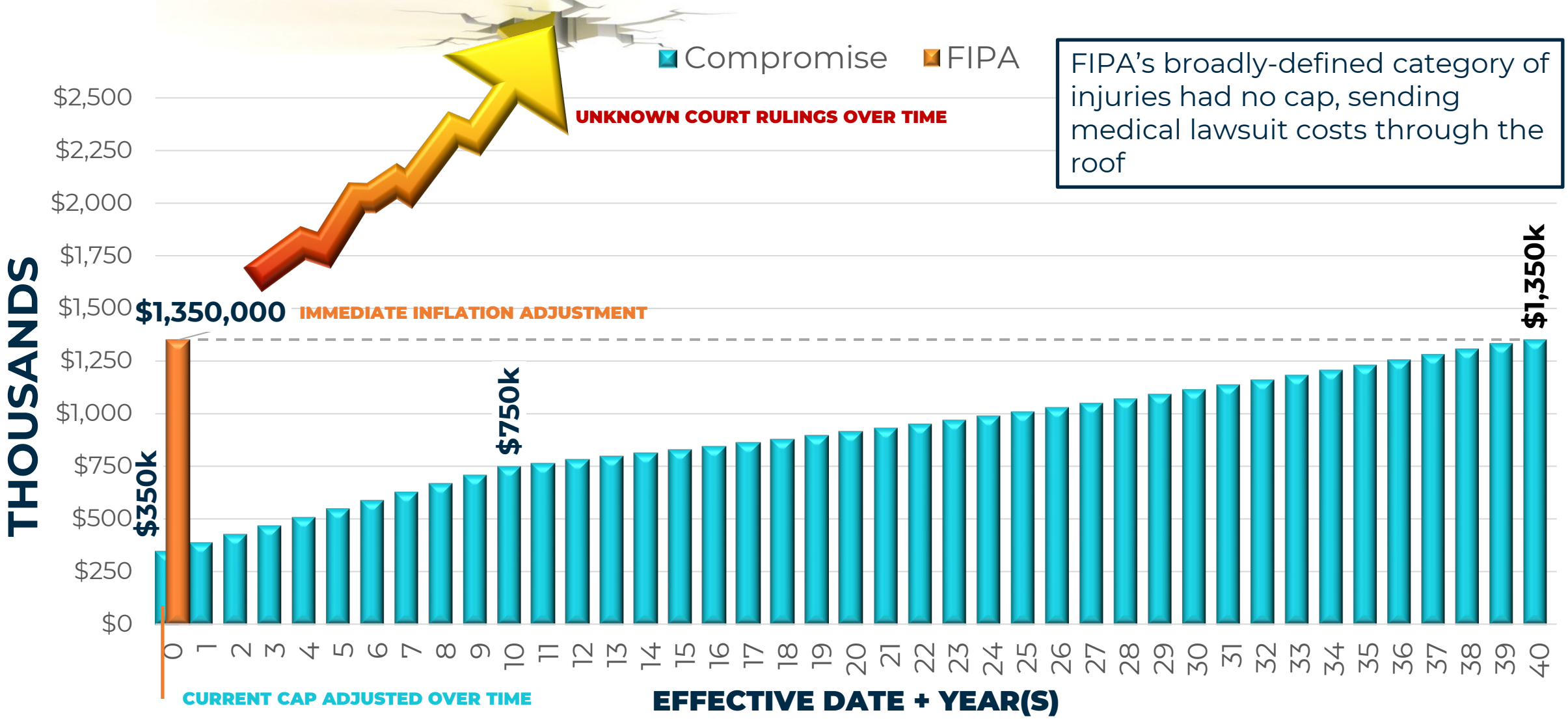
- The modernized framework establishes new evidentiary protection for all pre-litigation expressions of sympathy, regret, or benevolence, including statements of fault, in relation to pain, suffering or death of a patient or an adverse patient safety event or unexpected health care outcome.
- Often, a patient's decision to file a medical malpractice lawsuit is triggered by a failure in communication.
- Allowing physicians and patients to have a full and open conversation after an unexpected outcome will lead to greater accountability, patient safety and trust.

Modernizing and Updating MICRA

- Original limit on non-economic damages in medical malpractice cases: $250k
- While FIPA would have effectively eliminated the cap on non-economic damages entirely, under AB 35:
  - Cases not involving a patient death:
    - **$350k** as of January 1, 2023
    - gradually increasing over 10 years to **$750k**
  - Cases involving a patient death:
    - **$500k** as of January 1, 2023
    - gradually increasing over 10 years to **$1 million**
- 2% annual inflationary adjustment after 10 years
- Applies to cases filed and arbitration demanded on or after January 1, 2023[*1]
  - Does not apply to cases pending but filed before 1-1-23[*2])
- Cap in place at time of judgement or decision applies[*3]

CMA

Cap Comparison: AB 35 Compromise vs. FIPA



FIPA's broadly-defined category of injuries had no cap, sending medical lawsuit costs through the roof

CMA

Three New Cap Categories

AB 35 also created three categories, which may or may not apply depending on the facts of each particular case. In all cases, a health care provider or health care institution can only be held liable for damages under **one** category regardless of how the categories are applied or combined

- One cap for health care providers (regardless of the number of providers or causes of action)
- One cap for health care institutions (regardless of the number of institutions or causes of action)
- One cap for unaffiliated health care institutions or providers at that institution that commit a **separate and independent** negligent act

Key Takeaways: MICRA Modernization vs. FIPA

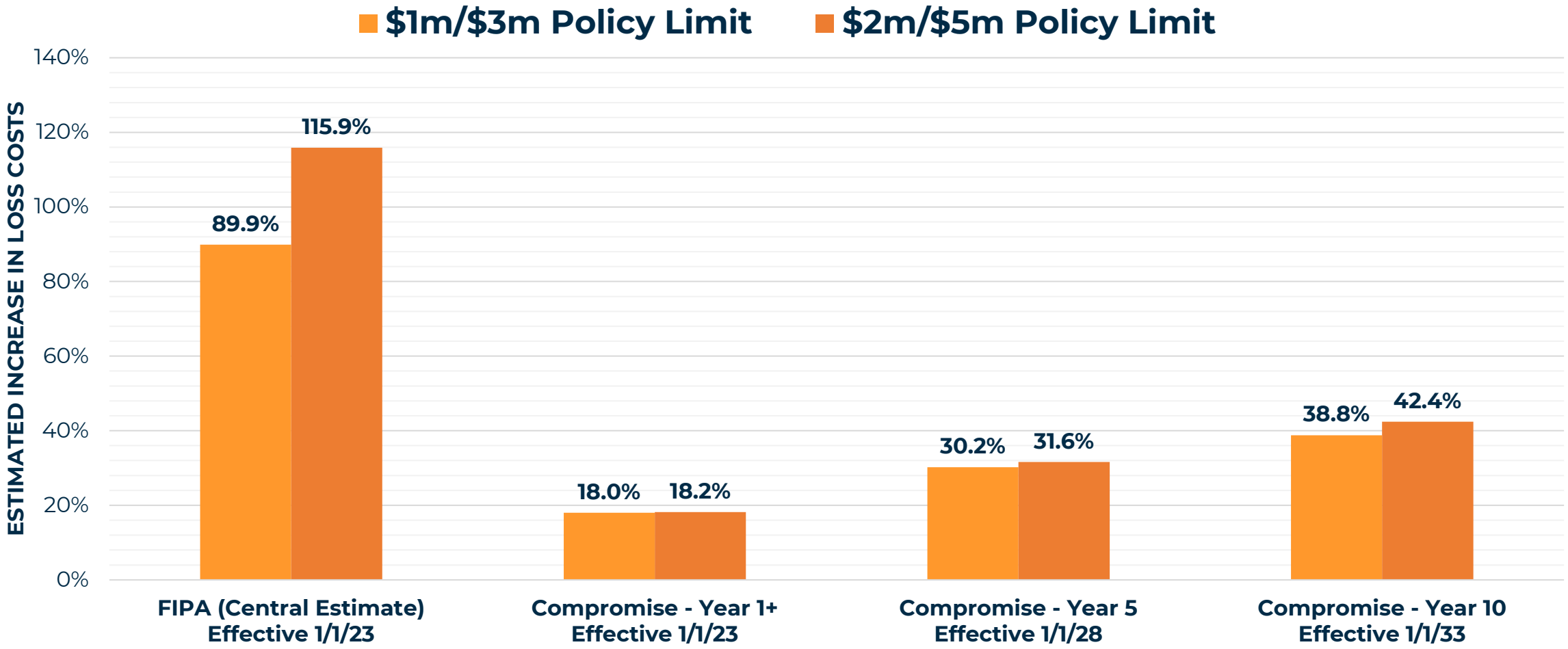
Key Provision	MICRA-Mod	FIPA
Option for binding arbitration	✓	✓
90-day advance notice of claim	✓	✓
Cap on non-economic damage awards	✓	UNLIMITED
One-year statute of limitations	✓	X
Allowing other sources of compensation to be considered in awards	✓	X
Limits on plaintiff's attorney's contingency fees	✓	X
The ability to pay awards over time	✓	X
Discovery and evidentiary protections for all pre-litigation expressions of sympathy, regret, or benevolence, and statements of fault by a provider to a patient/family	✓	X
Judicial discretion to throw out frivolous lawsuits[1]	✓	X
Limits on qualifications of expert witnesses[2]	✓	X
Protections from wage garnishments, liens & levies on personal assets[3]	✓	X
Protection from paying prevailing plaintiff's attorney fees out of pocket[4]	✓	X

FOOTNOTES: 1) FIPA creates a certificate of merit process that attorney can satisfy by stating that they attempted to contact three health care providers, but they declined or didn't respond; 2) FIPA expands who can testify as an expert against a health care provider; 3) FIPA includes a new requirement that medical negligence awards be satisfied by lien, levy, & wage garnishment on health care providers' personal assets; 4) FIPA contains a new mandate that health care providers pay prevailing plaintiff's attorney's fees in addition to damages (not reciprocal)

CMA

AB 35 – MICRA Modernization ~Early Impacts~

Estimated Changes in Physician MPLI Costs ~ as Projected in 2022~



Premium estimates provided to CMA by independent third-party actuarial firm.

CMA

Litigation Challenging AB35

- No known cases at this time
- Looking forward…
- Anecdotal attorney feedback
- Anecdotal provider feedback

Questions?

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Director of Corporate Affairs
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Thank You

MPL | MEDICAL PROFESSIONAL LIABILITY ASSOCIATION

The State of Medical Professional Liability

Mike Stinson, JM
Vice President, Public Policy and Legal Affairs
October 8, 2024

Analysis | Insight | Advocacy

Who we are

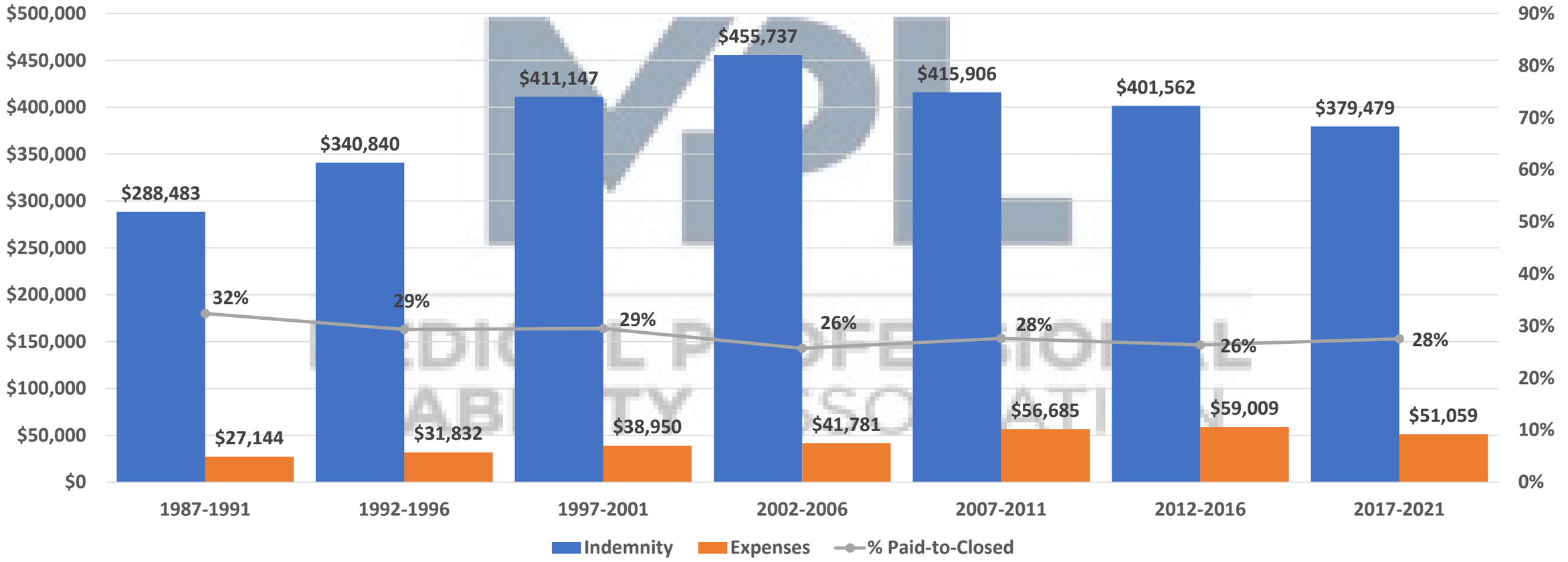
- Represent the diverse MPL industry
- Members insure all types of health professionals
- Members operate in all 50 states and dozens of countries

MPL ASSOCIATION
DATA SHARING PROJECT

EST. 1985

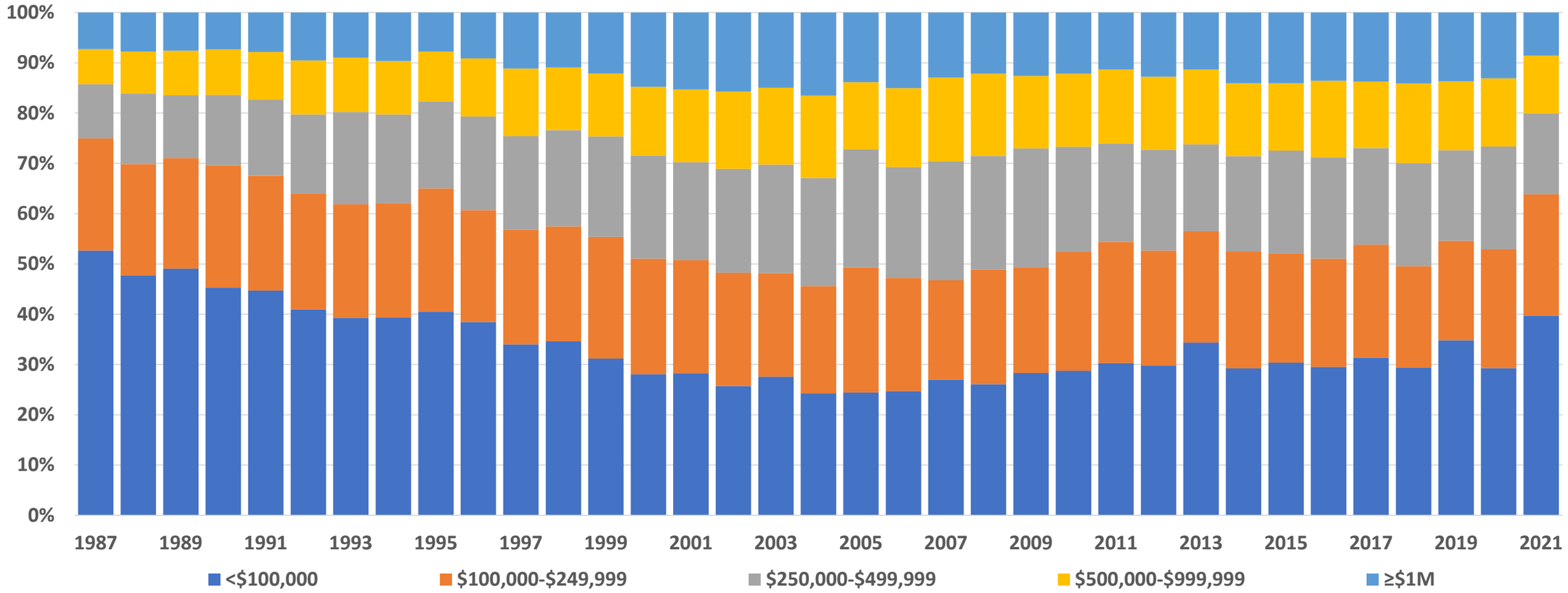
Costs of MPL Claims

Figure 1. Average Payments and % Paid-to-Closed by Close Year
For All Specialties (1987-2021)
2021 Dollars



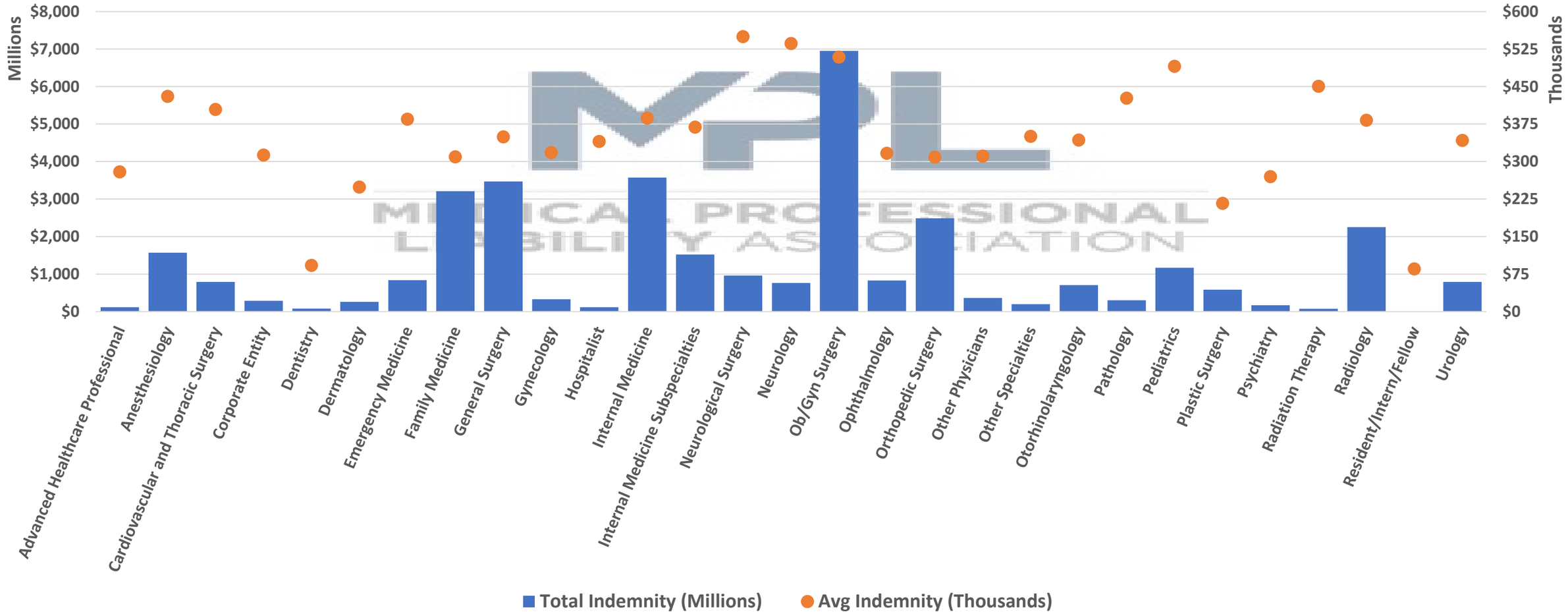
Claim Values

Figure 2. Percentage of Paid Claims by Indemnity Payment Threshold
For All Specialties (1987-2021)
2021 Dollars



Impact on Medical Specialties

Figure 3. Total and Average Indemnity Paid by Medical Specialty (1987-2021)
2021 Dollars



Escalating Damages

Nearly $47 million verdict won after Tennessee girl injured during birth

This is the largest verdict of its kind in Tennessee history

by Caleb Washington, *WSMV,* May 21, 2024 at 10:53 PM EDT

Rural Jury awards $47M medical-malpractice verdict

By Cedra Mayfield Law.com, August 8, 2024

Former lawyer who suffered stroke awarded $41 million in medical malpractice lawsuit

Craig Pierce, who lives in downstate Bushnell, is paralyzed on the left side of his body and has severe cognitive deficiencies as a result of the stroke.

By Cindy Hernandez Chicago Sun Times

MAY 10, 2024 — 8:15 PM EDT

Michigan mom, son awarded $120M in malpractice lawsuit over delayed C-section

by Christina Hall, Detroit Free Press

April 2, 2024, 11:51 p.m.

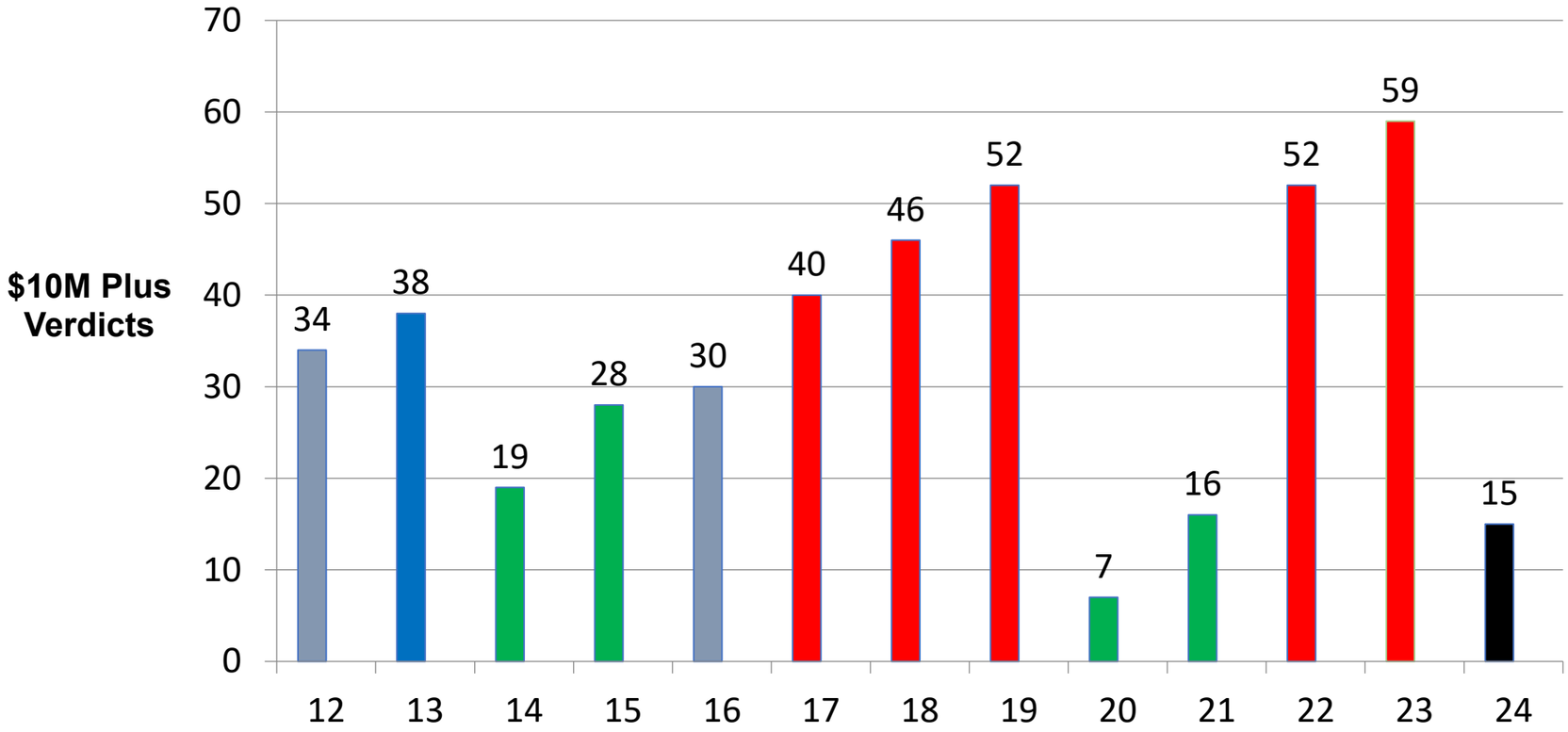
Philly jury hands down $182.7M med-mal verdict against UPenn Hospital, largest in Pa. history

By **Nicholas Malfitano**

Apr 28, 2023

$10M+ Verdicts, 2012-23

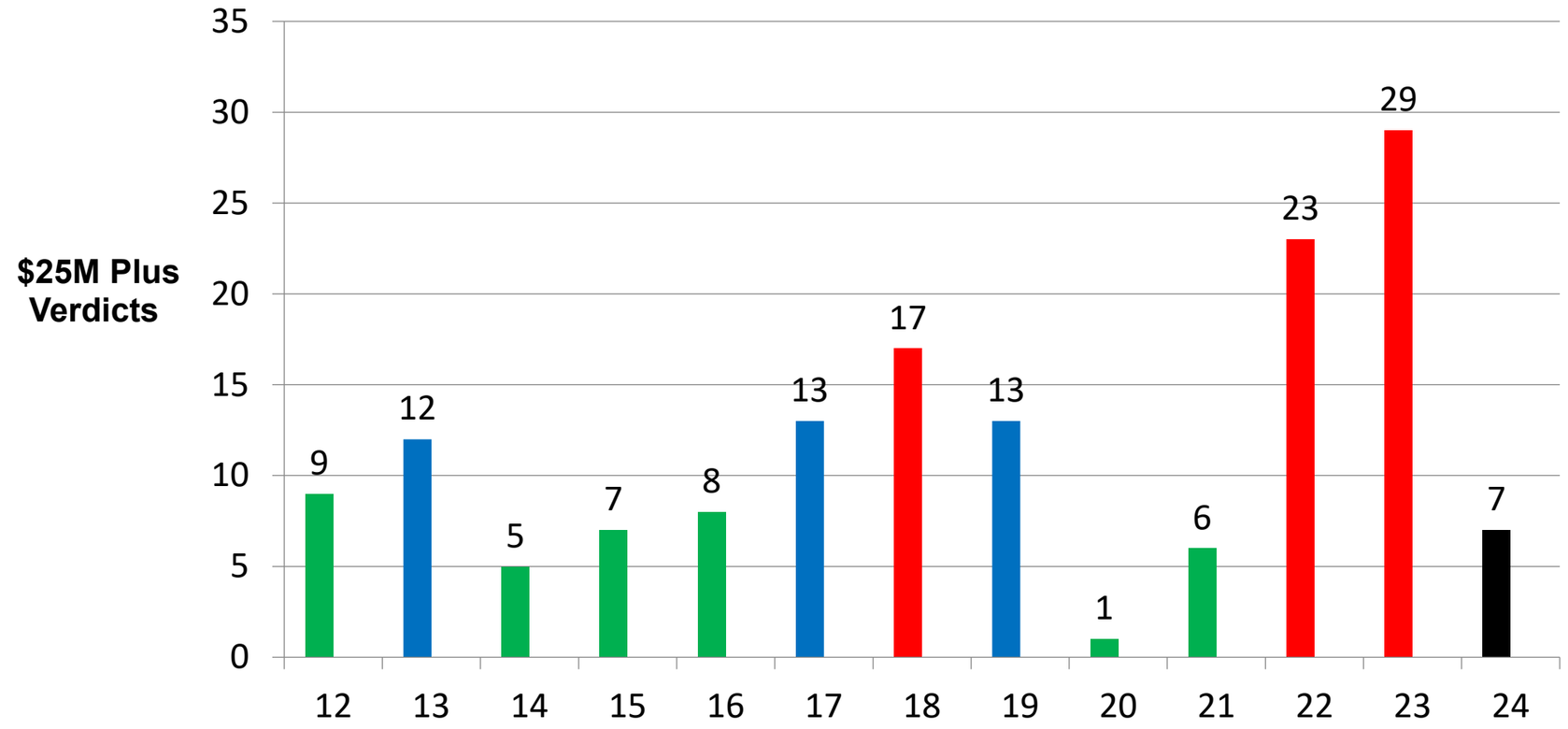
Data known as of 3/31/2024



TransRe
We value risk.

$25M+ Verdicts, 2012-23

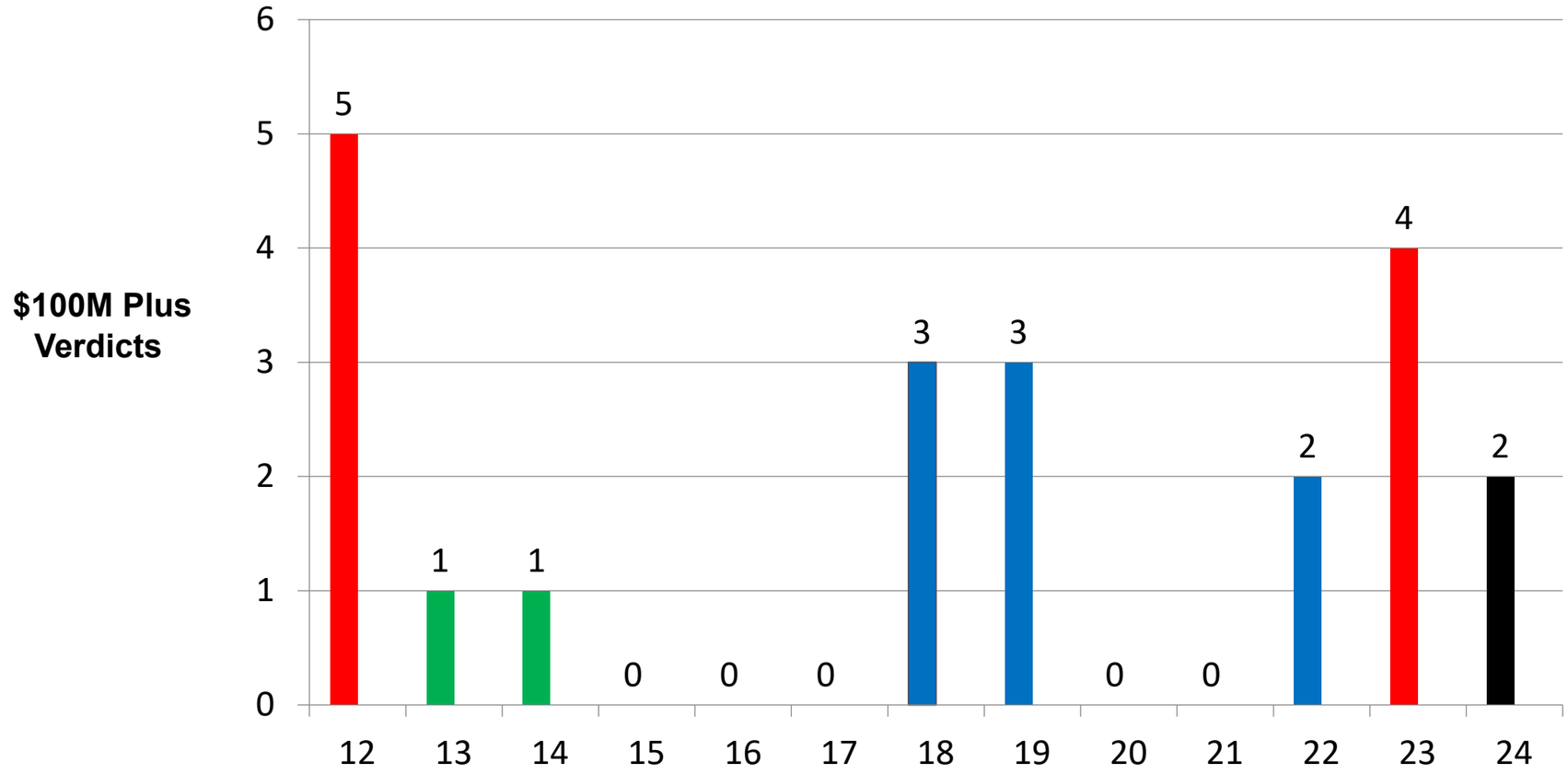
Data known as of 3/31/2024



TransRe
We value risk.

$100M+ Verdicts, 2012-23

Data known as of 3/31/2024



TransRe
We value risk.

Social Inflation

- Juries are changing
- Trial lawyer tactics
- Defense costs increasing
- Some insurers more aggressive

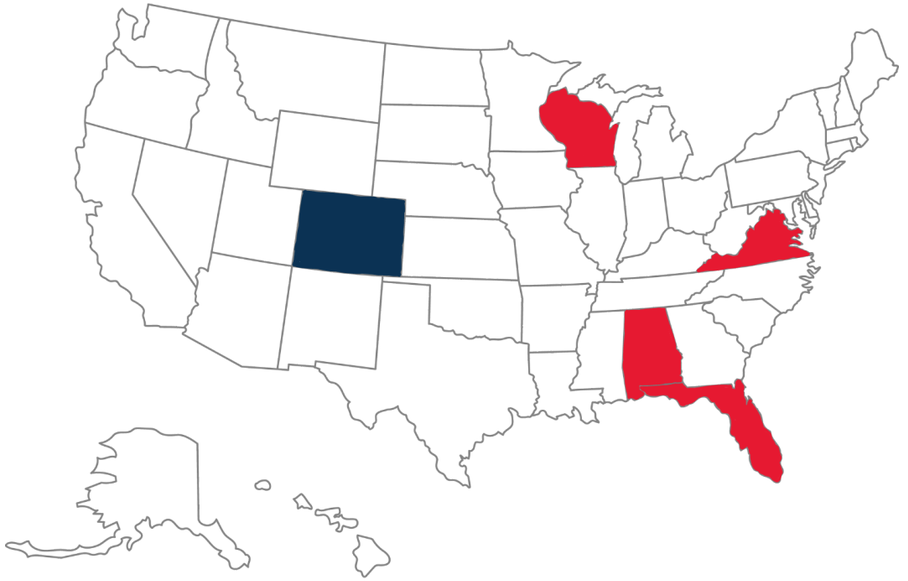
Damage Caps - 2024

Colorado (2024)

- Raises nonecon cap from $300k to $875k over 5 years
- Adjusted every two years for inflation starting 1/1/2030

Failed efforts

- FL (SB 248) – Establish $500k/$750k cap
- AL (SB 293) – Establish $1M cap
- WI (AB 872) – Increase cap to $3M
- VA (SB 493) – Eliminate caps for children <11



Damage Caps – 2023/2022

Iowa (2023)

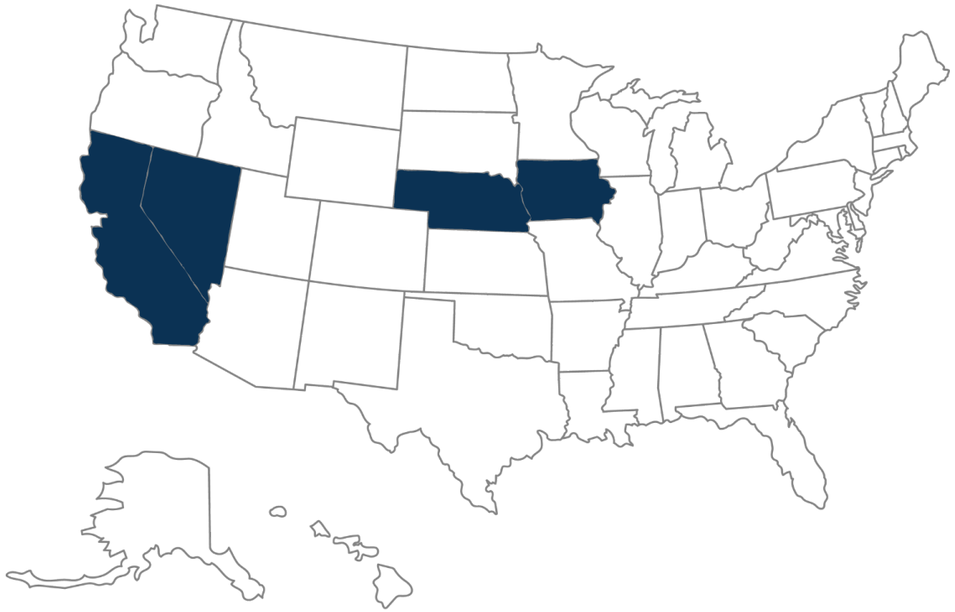
- Capped damages for severe injuries
- $1M for physicians/$2M for hospitals

Nevada (2023)

- Increases cap from $350K to $750K (over 5 years)
- 2.1% annual increase thereafter

Nebraska (2023)

- Increased cap from $500K to $800K
- PCS kicks in over that amount



California (2022)

- Raise cap to $350k for injuries/$500k for death; increases to $750k/$1M, then inflation
- Periodic payment threshold increased to $250k

Wrongful Death

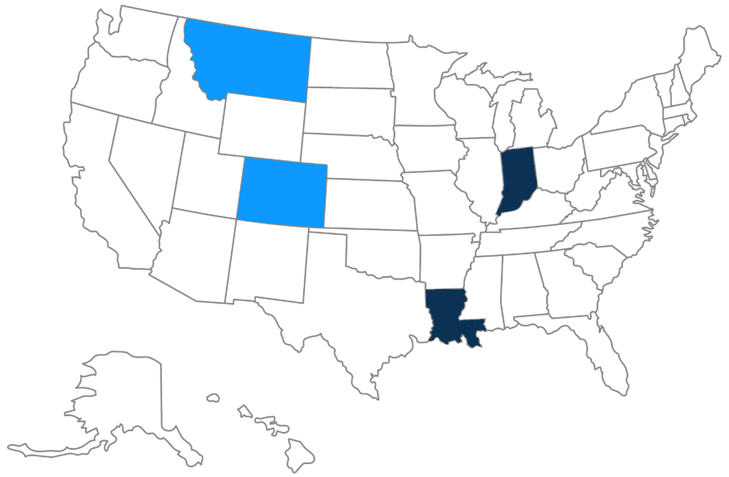
- New Hampshire
  - Increases wrongful death cap
  - $500k for an adult/$300k for a child
- New York (pending)
  - Expands family members who may file claims
  - Creates damages for “grief and anguish”

2023

- **Maine** – Increased wrongful death cap from $750K to $1M, w/annual inflation adjustments
- **New Jersey** – Expands eligibility to file claims
- **Rhode Island** – Increases floor from $250K to $350K

Third Party Litigation Funding

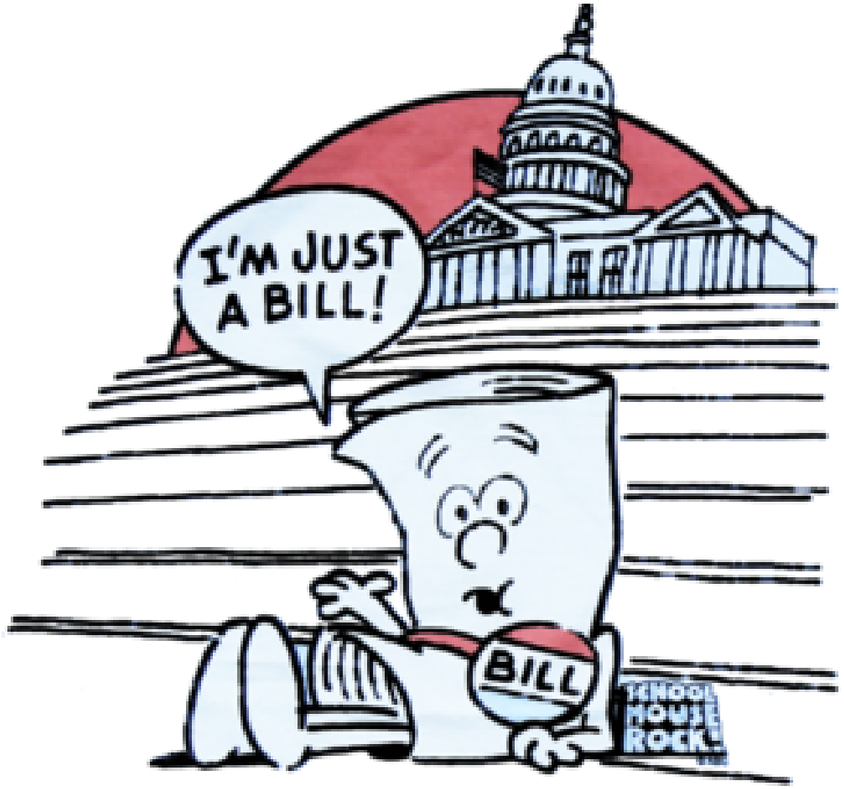
- Indiana
  - No involvement in case; discoverable
- Louisiana (foreign lenders only)
  - Mandates disclosure of funding agreements
  - No involvement in case



2023

- Indiana – Mandates disclosure of funding arrangements
- Montana – Mandates disclosure of funding arrangements
- Colorado – Regulatory reform proposal drastically weakened
- Louisiana – Disclosure bill vetoed

Other Issues



- Phantom damages
- Statutes of limitations
- Prejudgment interest
- Communication & Resolution Programs (CRPs)
- Anti-anchoring

Questions

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Government Relations Risk Management: Navigating this Important Member Benefit

OUR PANEL

- George Cox, JD, American Medical Association
- Grant M. Achenbach, JD, Krieg DeVault LLP
- Robert Kane, JD, Illinois State Medical Society
- Tom Conley, JD (Moderator), Saul Ewing LLP

Lawyers as Lobbyist

- Lobbying is an attempt to influence government action through written or oral communication.
- Advocacy does not always constitute the practice of law
- When lobbying, are you acting as a lawyer or performing nonlegal services?
  - Client expectations
    - State Law and Rules
    - Notice to client
  - Attorney-Client privilege
  - Conflicts of Interest
  - Government representative belief

Lobbying Disclosure Act (LDA)

- The LDA was enacted in 1995 to increase transparency in lobbying activities.
- Purpose: To ensure that lobbying efforts directed at influencing federal law and policy are disclosed to the public and Congress.
- Key Players: The law primarily affects lobbyists, lobbying firms, and organizations engaging in lobbying activities.
- Honest Leadership and Open Government Act (HLOGA) of 2007.
  - Strengthened public disclosure requirements concerning lobbying activities and funding.
  - Placed more restrictions on gifts to Members of Congress and their staff.

Key Provisions of the LDA

- Registration Requirements: Lobbyists must register with the Secretary of the Senate and the Clerk of the House of Representatives.
- Quarterly Reporting: Lobbyists and lobbying organizations are required to file quarterly reports detailing their lobbying activities and expenses.
- Semi-Annual Reporting: Lobbyists and lobbying organizations are required to file semi-annual reports disclosing political contributions of $200 or more and certify they read and complied with the House and Senate gift rules.
- Definition of Lobbying: The act defines lobbying activities broadly.

Who is a Lobbyist?

- A lobbyist is anyone who is compensated for engaging in lobbying contacts with federal officials and who spends over 20% of their time on such activities over a three-month period.
- Key Criteria:
  - Makes more than one lobbying contact.
  - Spends at least 20% of their time lobbying during a quarter.
  - Engages with executive or legislative branch officials to influence policy.

What are Lobbying Contacts?

- Lobbying contacts are oral (virtual or in person) or written communications (e.g., emails, texts) to a covered legislative/executive branch official to influence federal legislation, regulations, Executive Orders, policies, programs, contracts, or nominations.
- Exemptions:
  - Formal proceedings: rulemaking, litigation
  - Response to a request
  - Request for meeting
  - Request for status of legislation
  - Testimony at congressional hearings
  - Participation on an advisory committee
  - Grassroots;* communications compelled by a federal contract, grant, license; other exemptions

What are Lobbying Activities?

- Lobbying contacts.
- Any effort in support of such contacts.
  - Preparation or planning activities, research, and other background work
  - Intended, at time of its preparation, for use in contacts and coordination with the lobbying activities of others.
- Note: Activities that are not lobbying contacts because of an exception may nevertheless be lobbying activities if they support lobbying contacts (e.g., preparing testimony may be lobbying activity if testimony is used to support lobbying contacts).

Who is a “covered” official?

- Congress:
  - Member, Delegate, officer, employee, or paid intern
- Executive Branch-**LDA Definition**:
  - The President and Vice President
  - Officers and employees of the Executive Office of the President
  - Executive Schedule Level I–V officials and employees
  - Uniformed services members with a pay grade of 0–7 or higher
  - Schedule C employees

LDA vs IRC Definition

- The LDA permits 501(c)(6) organizations (e.g., professional associations) required to file under the Internal Revenue Code (IRC) (e.g., Form 990) to use the IRC definition of lobbying in lieu of the LDA definitions for determining "contacts" and "lobbying activities" for the Executive Branch.
- Executive Branch-**IRC Definition**:
  - The President and Vice President
  - Cabinet officers and their immediate deputies (e.g., Secretary and Deputy Secretary of the Department of Health & Human Services)
  - Any officer or employee of the White House Office of the Executive Office of the President
  - The two most senior level officers of each of the other agencies in the Executive Office of the President (e.g., Office of Science and Technology Policy, Office of National Drug Control Policy, Office of Management and Budget)

LDA vs IRC Definition

- The LDA covers contacts with **federal** officials.
- The IRC's definition includes contacts made with federal, **state**, and **local** officials.
- *The IRC's definition is broader in scope, covering more types of lobbying activities, including grassroots lobbying and broader efforts to influence the public.

Gift Rules for Lobbyists

- The Basic Rule:
  - A lobbyist or an entity that employs or retains a lobbyist (e.g., AMA) may not give any “thing of value” (gift) to a member, officer, or employee of the House, Senate, or Executive Branch.
- Four Questions:
  - Is it a gift?
  - Is it to a prohibited recipient?
  - Is it from a prohibited source?
  - Does it meet an exception?
- When in doubt, ASK.

Lobbying Compliance Plan—Key Elements

- Review methodology to determine whether or not to register
  - Understand reporting method used
  - Who is listed as a lobbyist
  - Which other employees & activities support lobbying
- Establish appropriate accounting and record keeping systems
- Establish employee education & training program
  - For employees interacting with federal officials or supporting those activities
  - Overall framework & culture of compliance
  - Ethics rules re gifts, meal & travel
  - Reporting of time & expenses
  - Consider formal HR policy and signed certificates for registered lobbyists
- Review in advance all activities that may involve gifts
- Appoint individual to review/approve activities that may trigger compliance issues
- Establish procedures for timely filings of LD-2, LD-203
- Occasional self-audit

State Lobbying Regulations

- Definition of lobbying, lobbyists, legislative persons
- Registration requirements:
  - Entities
  - Individuals
- Prohibited conduct
  - Gifts/entertainment
  - Cooling off periods
- Reporting requirements:
  - Entertainment expenses
  - Gifts
- Executive Branch lobbying

State Political Action Committees

- Register with State Election Division
  - Consider strategy of State v. Federal PAC
- Organizational considerations (bylaws, purpose, affiliation)
- Fundraising
  - Permissible sources
  - Disclaimer language
- Contribution and expenditure limits
- Reporting cycle
- Ethical considerations (no “quid pro quo”)

Can a Medical Society Lawyer-Lobbyist Have a Conflict of Interest?

What is a conflict of interest?

- In law, a conflict of interest refers to a situation where the interests of an attorney, a different client, or a third-party conflict with the interests of the present client. It arises when an individual is in a position to exploit their professional capacity for their own benefit. A conflict of interest exists if the circumstances are reasonably believed to create a risk that a decision may be unduly influenced by other, secondary interest. It is a term used to describe the situation in which a public official or fiduciary exploits the relationship for a personal benefit.

- A conflict of interest arises when **what is in a person's best interest is not in the best interest of another person or organization to which that individual owes loyalty**.

Can a Medical Society Lawyer-Lobbyist Have a Conflict of Interest?

ABA Model Code of Professional Responsibility

- Rule 1.7: Conflict of Interest: Current Clients
- Rule 1.8: Current Clients: Specific Rules
- Rule 1.10: Imputation of Conflicts of Interest: General Rule
- Rule 1.11: Special Conflicts of Interest for Former & Current Government Officers & Employees
- Rule 5.7 Responsibilities Regarding Law-related services

Ethical Guidance

Do Rules of Professional Conduct Apply to Lobbyists?

- *ABA Model Rules of Professional Conduct: Preamble and Scope*

[3] There are Rules that apply to lawyers who are not active in the practice of law or to practicing lawyers even when they are acting in a nonprofessional capacity.

[5] A lawyer's conduct should conform to the requirements of the law, both in professional service to clients and in the lawyer's business and personal affairs.

[9] Virtually all difficult ethical problems arise from conflict between a lawyer's responsibilities to clients, to the legal system and to the lawyer's own interest in remaining an ethical person while earning a satisfactory living.

Model Rule 1.13: Organization as Client

(a) A lawyer employed or retained by an organization represents the organization acting through its duly authorized constituents.

(b) If a lawyer for an organization knows that an officer, employee or other person associated with the organization is engaged in action, intends to act or refuses to act in a matter related to the representation that is a violation of a legal obligation to the organization, or a violation of law that reasonably might be imputed to the organization, and that is likely to result in substantial injury to the organization, then the lawyer shall proceed as is reasonably necessary in the best interest of the organization. Unless the lawyer reasonably believes that it is not necessary in the best interest of the organization to do so, the lawyer shall refer the matter to higher authority in the organization, including, if warranted by the circumstances to the highest authority that can act on behalf of the organization as determined by applicable law.

Model Rule 1.13: Organization as Client

(c) Except as provided in paragraph (d), if

(1) despite the lawyer's efforts in accordance with paragraph (b) the highest authority that can act on behalf of the organization insists upon or fails to address in a timely and appropriate manner an action, or a refusal to act, that is clearly a violation of law, and

(2) the lawyer reasonably believes that the violation is reasonably certain to result in substantial injury to the organization, then the lawyer may reveal information relating to the representation whether or not Rule 1.6 permits such disclosure, but only if and to the extent the lawyer reasonably believes necessary to prevent substantial injury to the organization.

(d) Paragraph (c) shall not apply with respect to information relating to a lawyer's representation of an organization to investigate an alleged violation of law, or to defend the organization or an officer, employee or other constituent associated with the organization against a claim arising out of an alleged violation of law.

Model Rule 1.13: Organization as Client

(e) A lawyer who reasonably believes that he or she has been discharged because of the lawyer's actions taken pursuant to paragraphs (b) or (c), or who withdraws under circumstances that require or permit the lawyer to take action under either of those paragraphs, shall proceed as the lawyer reasonably believes necessary to assure that the organization's highest authority is informed of the lawyer's discharge or withdrawal.

(f) In dealing with an organization's directors, officers, employees, members, shareholders or other constituents, a lawyer shall explain the identity of the client when the lawyer knows or reasonably should know that the organization's interests are adverse to those of the constituents with whom the lawyer is dealing.

Model Rule 3.9 Advocate in Nonadjudicative Proceeding

A lawyer representing a client before a legislative body or administrative agency in a nonadjudicative proceeding shall disclose that the appearance is in a representative capacity.

[1] In representation before bodies such as legislatures, municipal councils, and executive and administrative agencies acting in a rule-making or policy-making capacity, lawyers present facts, formulate issues and advance argument in the matters under consideration. The decision-making body, like a court, should be able to rely on the integrity of the submissions made to it. A lawyer appearing before such a body must deal with it honestly and in conformity with applicable rules of procedure. See Rules 3.3(a) through (c), 3.4(a) through (c) and 3.5.

[2] Lawyers have no exclusive right to appear before nonadjudicative bodies, as they do before a court. The requirements of this Rule therefore may subject lawyers to regulations inapplicable to advocates who are not lawyers. However, legislatures and administrative agencies have a right to expect lawyers to deal with them as they deal with courts.

[3] This Rule only applies when a lawyer represents a client in connection with an official hearing or meeting of a governmental agency or a legislative body to which the lawyer or the lawyer's client is presenting evidence or argument. It does not apply to representation of a client in a negotiation or other bilateral transaction with a governmental agency or in connection with an application for a license or other privilege or the client's compliance with generally applicable reporting requirements, such as the filing of income-tax returns. Nor does it apply to the representation of a client in connection with an investigation or examination of the client's affairs conducted by government investigators or examiners. Representation in such matters is governed by Rules 4.1 through 4.4.

Ethical Dilemmas

- Conflicts in different objectives of different members of the organization.
  - Different specialties
  - Different employment settings
  - Different cultural, religious and moral beliefs
- Coalitions and Joint Advocacy
- Building Membership
  - Grassroots
  - Grasstops
  - Key contacts

AI Generated

Ethical Dilemmas

- Communication with Non-members
- Public Advocacy
  - Media Relations
  - Advertising
  - Social Media and Website
- Political Action Committees

AI Generated

Conflict of Interest Scenarios

Are any of these situations a conflict of interest?

- Medical society lobbyist representing third party clients-specialty societies.
- Medical society lobbyist renting an apartment to a legislator.
- Medical society lobbyist testifying both in support and opposition to legislation.
- Medical society lobbyist promising support for a position contrary to medical society stated position.

Conflict of Interest Guideposts

Things to be aware of in lobbying:

- Always know your client.
- Be clear and honest on lobbying-reputational risk.
- Abraham Lincoln advice:
  - Be sure you put your feet in the right place, then stand firm
  - Whatever you are, be a good one

Case Study: Managing Policy Conflicts

- Indiana environment:
  - Highly charged legislative issue
  - Grassroots movement in physician community
- Lack of understanding of:
  - Political and legislative process
  - Medical association organization, structure, policymaking process
- Perception of a lack of transparency
- Challenge, but also an opportunity

Case Study: Managing Policy Conflicts

- Solution: ISMA Pulse
- Online forum for members to directly engage in dialogue and provide input on policy proposals
- Outside of the House of Delegates, used by reference committees
- Benefits:
  - Member engagement in policymaking (and new membership)
  - Increased awareness of issues and processes
  - Member satisfaction of having their voice heard
- Drawbacks:
  - “Social media”
  - Polarization and politicization of issues

Indiana Physician Coalition

- Inspired by alignment of medical association and specialty associations on scope of practice issues
- Informal umbrella organization, separately branded
- Regular meetings facilitated and staffed by ISMA
- “Dues” contributions to fund:
  - Grassroots tools
  - PR campaigns
  - Public surveys and data gathering

QUESTIONS?

CALIFORNIA MEDICAL ASSOCIATION

California Provider Shield Laws Post-*Dobbs*

Sheirin Ghoddoucy
Senior Legal Counsel
California Medical Association

October 9, 2024

CMA

California Legal Shields

Decriminalize Abortion/Pregnancy Loss (AB 2223, 2022)

Prohibit State Court Enforcement of Out-of-State Laws

- Enforcement of OOS Abortion Laws, Civil Liability/Judgements (AB 1666, 2022)
- Surveillance of Abortion, Enforcement of OOS Prosecutions (AB 1242, 2022)
- Enforcement of OOS Subpoenas (AB 2091, 2022)

Protect Apprehension of CA Abortion Providers

- Prohibit Warrants, Surveillance, or Bail Agent/Bounty Hunter Apprehension of CA Individuals for OOS Criminal Proceeding, Regardless of Patient Location (SB 345, 2023)

Prohibit Professional Discipline/Licensure Actions

- Medical Board Discipline of Licensees (AB 2626, 2022)
- Adverse Actions in Provider Licensure (AB 2626, 2022; SB 345 & 385, 2023)
- Adverse Actions/Discipline by Healing Arts Board based on OOS Law/Action (SB 345, 2023)

California Legal Shields

Prohibit Adverse Actions in Practice & Contracts

- in Medical Malpractice Insurance (AB 571, 2023)
- by Facility Admitting Privileges, Medical Staff Membership (AB 1707, 2023)
- in Commercial Plan-Provider Contracts, Participation in Medicaid (SB 487, 2023)

Privacy Protections Prohibit Disclosure of

- Information in Response to Foreign Subpoenas (AB 2091, 2022)
- Sensitive Service Records to Data Exchanges (AB 352, 2023)
- Reproductive Health Application Data by Non-Covered Entities (AB 254, 2023)
- Consumer Digital Reproductive Health Data (AB 1194, 2023) (closed exception in CA Consumer Privacy Act for risk/danger of death or injury to natural person)

Shield Laws in Action

+ OOS subpoenas for abortion and gender affirming care
+ Tele-MAB implications

Thank You

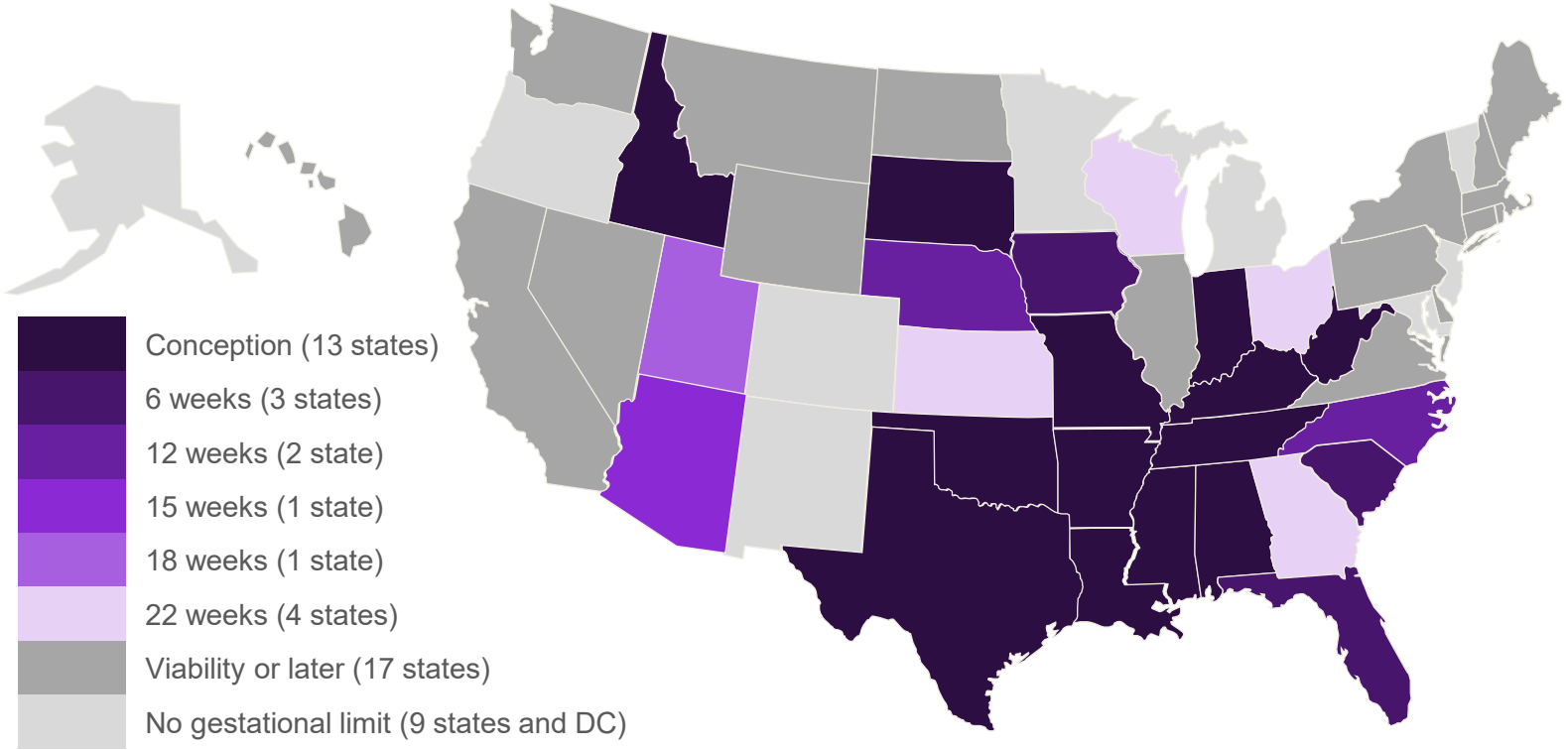
sghoddoucy@cmadocs.org

AMA
AMERICAN MEDICAL ASSOCIATION

Reproductive Healthcare Across State Lines

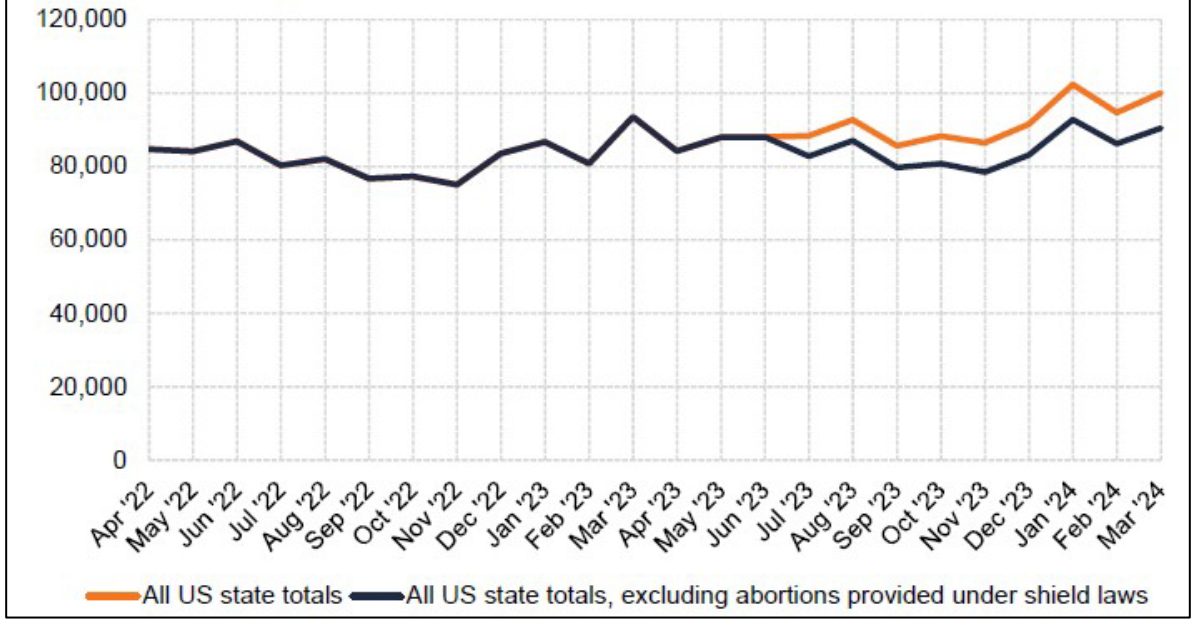
Annalia Michelman
Senior Attorney
AMA Advocacy Resource Center

State Abortion Bans (as of October 7, 2024)



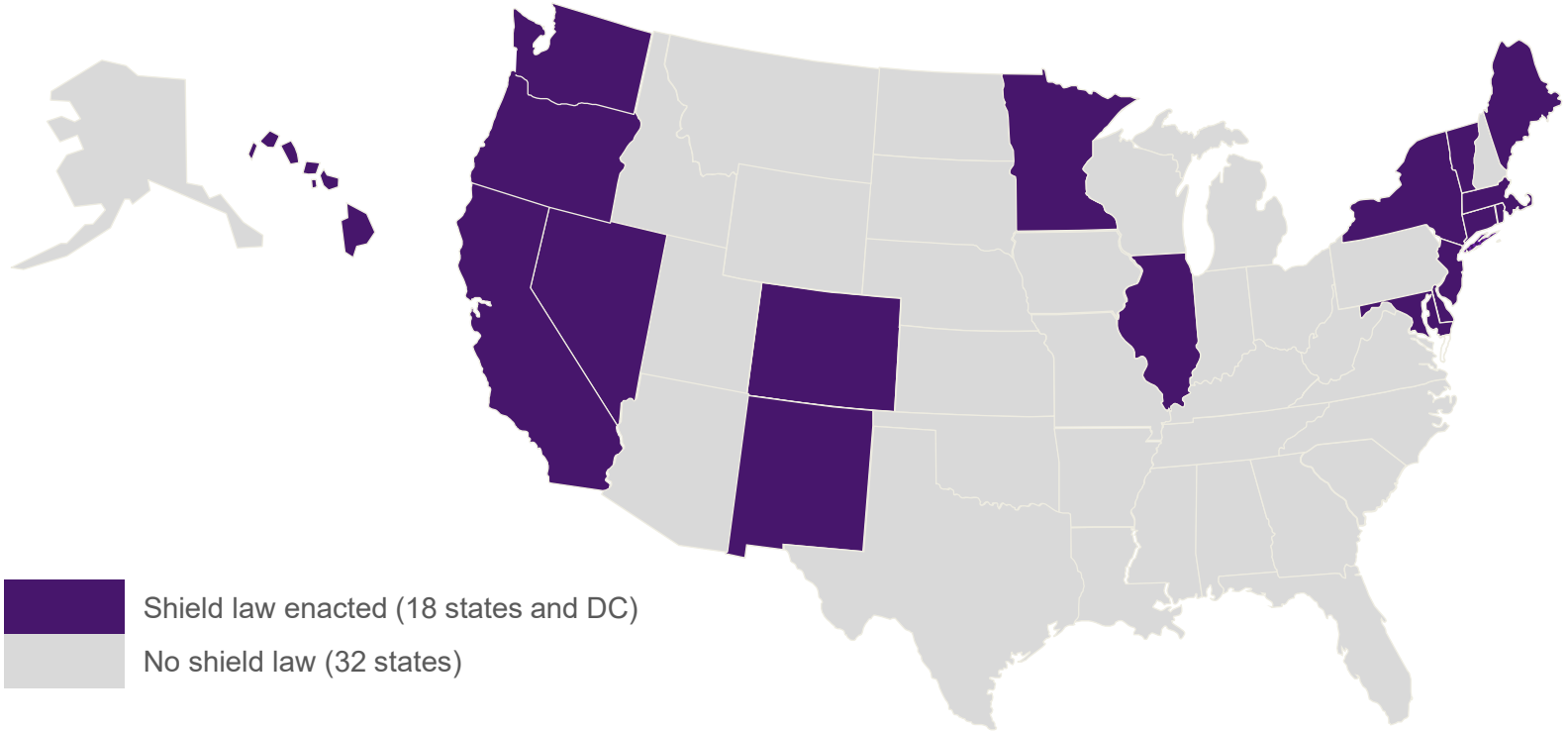
Since the *Dobbs* decision, the total number of abortions provided per month has increased.

Figure 1. Abortions in the US from April 2022 to March 2024 (both including and excluding abortions provided under shield laws)



Source: Society of Family Planning, #WeCount Report, April 2022 to March 2024, Released August 7, 2024

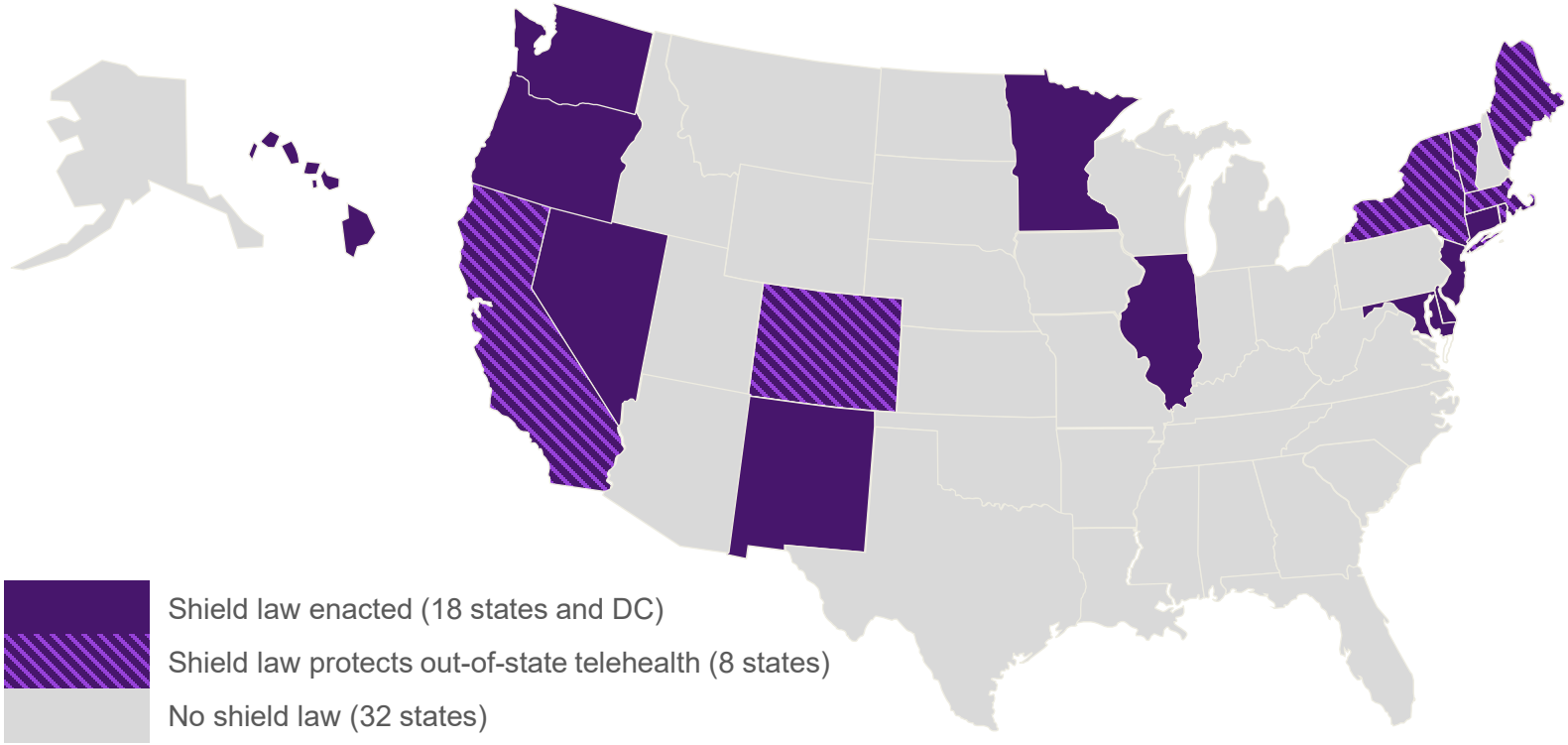
State Shield Laws for Abortion Care (as of October 7, 2024)



Shield Law Protections

- Out-of-state Legal Actions or Investigations
- Professional Disciplinary Actions
- Civil Liability
- Insurance Actions
- Confidentiality

State Shield Laws for Abortion Care (as of September 27, 2024)



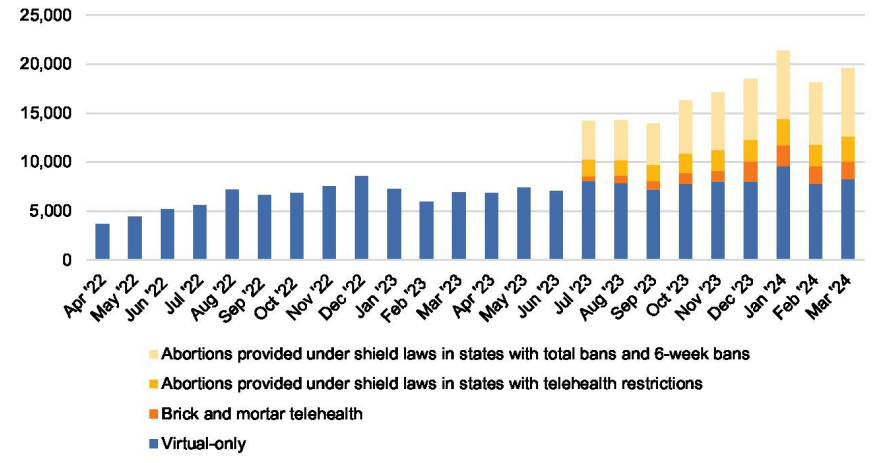
Shield law enacted (18 states and DC)

Shield law protects out-of-state telehealth (8 states)

No shield law (32 states)

Over 6,700 monthly telehealth abortions are provided under shield laws to people in states with total or 6-week abortion bans.

Figure 6. Telehealth abortions in the US from April 2022 to March 2024 (includes abortions provided under shield laws, July 2023 to March 2024)



Note: Prior to July 2023, brick and mortar telehealth abortions were categorized as in-person.

Source: Society of Family Planning, #WeCount Report, April 2022 to March 2024, Released August 7, 2024

The Guardian

New laws help people in US states with bans get abortion pills: 'Most people don't know it's available'

'Shield laws' allowed medical providers to ship pills to over 40,000 pe… months of…

Carter Sher…

Tue 14 May 2024

Over the las… over 40,00… laws" that p… restrictions…

Researchers… studies the… Wade, first… 2023. In its… laws passed… Vermont an…

The Washington Post

Blue-state doctors launch abortion pill pipeline into states with bans

At least 3,500 doses have been shipped to antiabortion states since mid-June, a process enabled by new shield laws

July 19, 2…

The doctor start…

Sitting in her ba… list of towns and…

A month ago, a… unexpected preg… pills they receiv…

Then, all of a su…

The New York Times

Abortion Shield Laws: A New War Between the States

Doctors in six states where abortion is legal are using new laws to send abortion pills to tens of thousands of women in states where it is illegal.

By Pam Belluck

Pam Belluck spent time with abortion providers sending pills to states that outlaw abortion and talked with patients receiving those pills.

Published Feb. 22, 2024 Updated Feb. 23, 2024

Behind an unmarked door in a boxy brick building outside Boston, a quiet rebellion is taking place. Here, in a 7-by-12-foot room, abortion is being made available to thousands of women in states where it is illegal.

The patients do not have to travel here to terminate their pregnancies, and they do not have to wait weeks to receive abortion medication from overseas.

Instead, they are obtaining abortion pills prescribed by licensed Massachusetts providers, packaged in the little room and mailed from a nearby post office,

Understanding Shield Law Limitations

Ban State Responses

- Abortion trafficking laws
- Abortion fund litigation
- Abortion medication restrictions
- Local government actions

Other Potential Developments

- Abortion medication approval
- Comstock Act enforcement

Physicians' powerful ally in patient care

IVF
ALABAMA ACT 2024-20

What underlying action led to Supreme Court decision?

What did the Supreme Court opinion really say?

What does the Act do?

IVF – UNDERLYING ACTION ⚖

- An unauthorized individual accessed a cryopreservation tank containing frozen embryos in an IVF clinic and removed some of the embryos
- Three affected families sued the IVF clinic and the adjoining hospital where the unauthorized individual entered the IVF clinic, claiming the defendants were responsible for the "wrongful death" of the embryos
- The defendants filed motions to dismiss each of the actions, claiming that a frozen embryo should not be considered a "minor child" for purposes of the Alabama Wrongful Death of a Minor Act
- The trial court granted the motions, dismissing the actions
- The plaintiffs appealed the trial court's order dismissing the actions, claiming that "minor child" is not defined under the Alabama Wrongful Death of a Minor Act, and therefore, a frozen embryo could be considered a minor child for purposes of the Act
- The Supreme Court's opinion overruled the trial court's granting of the defendants Motions to Dismiss, and the legislature's statutory fix from the 2024 Regular Session has no bearing on the underlying case, so it is still pending

IVF – SUPREME COURT OPINION

- The Supreme Court reversed the trial court's order dismissing all the actions, holding that the term "minor child" under the Alabama Wrongful Death of a Minor Act includes any unborn child, regardless of stage of development and regardless of location
- Summary of points that led to conclusion
  - The legislature elected NOT to define "minor child" when the Wrongful Death of a Minor Act was passed (in 1876)
  - Older court interpretations of the term "minor child" included unborn children only if they were considered viable, but more recent opinions extended the definition of "minor child" to include unborn children at any stage of development
  - Criminal statutes in Alabama, including those related to homicide and also those that prohibit abortion, define a "person" and an "unborn child," respectively, to include the unborn ***in utero*** at any stage of development, but despite the defense arguments that civil remedies should be consistent with criminal ones, the Supreme Court sided with the plaintiffs, concluding it was more important for there to be a civil remedy in every instance where a criminal remedy was available than for those to be consistent
  - The Court opined that the inconsistency issue was the Legislature's problem to fix

IVF – LEGISLATIVE ACT 2024-20

From SB159

Section 1 protects the physicians, staff and practices who perform IVF from criminal actions or prosecutions

It is to be applied retroactively, except for any action already pending, i.e., the underlying action.

Why? Alabama Constitution, Section 95, in part:

"After suit has been commenced on any cause of action, the legislature shall have no power to take away such cause of action, or destroy any existing defense to such suit."

BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

Section 1. (a) Related to in vitro fertilization and notwithstanding any provision of law, including any cause of action provided in Chapter 5 of Title 6, Code of Alabama 1975, no action, suit, or criminal prosecution for the damage to or death of an embryo shall be brought or maintained against any individual or entity when providing or receiving services related to in vitro fertilization.

(b) This section is intended to apply retroactively to any act, omission, or course of services which are not the subject of litigation on the effective date of this act.

IVF – LEGISLATIVE ACT 2024-20

From SB159

Section 2 protects manufacturers of products used to facilitate IVF and transporters of stored embryos.

It prohibits criminal prosecution and limits damages in civil action to the cost of the impacted IVF cycle.

It is to be applied retroactively, with no underlying action currently pending.

Section 2.(a) Related to in vitro fertilization and notwithstanding any provision of law, including any cause of action provided in Chapter 5 of Title 6, Code of Alabama 1975, for the damage to or death of an embryo brought against the manufacturer of goods used to facilitate the in vitro fertilization process or the transport of stored embryos, damages shall be limited to compensatory damages calculated as the price paid for the impacted in vitro cycle.

(b) Related to in vitro fertilization and notwithstanding any provision of law, no criminal prosecution may be brought for the damage to or death of an embryo against the manufacturer of goods used to facilitate the in vitro fertilization process or the transport of stored embryos.

(c) This section is remedial in nature and is intended to apply retroactively.

IVF – LEGISLATIVE ACT 2024-20

- Is it enough?
  - It allows IVF clinics to continue to practice in Alabama…for now…without fear of prosecution or costly damage awards
  - It also protects manufacturers of goods used in the IVF process and transporters of frozen embryos
- But…
  - It does not address the Supreme Court's implied definition of when life begins
  - It is vulnerable to constitutional challenges because of the blanket immunity provisions
- Of note – Supreme Court has denied an application for rehearing since Act 2024-20 was passed
- All of the families involved in the underlying action except for one have agreed to a settlement

Reproductive Healthcare: The Impact of IVF Court Cases

Kelly Walla, JD, LLM

Texas Medical Association

Vice President & General Counsel

Antoun v. Antoun – Texas appellate court decision

- 2nd District, Fort Worth Appellate Court
- Decision: July 13, 2023
- 1st time post-*Dobbs* where the appellate court was asked whether a trial court abused its discretion in awarding rights to frozen embryos in a divorce decree.

Antoun v. Antoun – Appellate Court decision

Couple had signed “Consent Form Cryopreservation of Embryos" on May 10, 2019 with Dallas Fertility Clinic.

- June 29, 2022 - court awards the embryos to husband per the agreement.
- June 29, 2022 - final order of divorce

- July 24, 2022 - *Dobbs* decision
- July 26, 2022 - wife files a "Motion for Reconsideration of Disposition of Embryos After of [sic] Change in Law."
- August 1, 2022 - wife's motion for reconsideration denied, and the court sigsns an "Order [Denying] Petitioner's Motion for Reconsideration of Disposition of Embryos

Antoun v. Antoun

- August 25, 2022 - Texas Human Life Protection Act goes into effect.
- August 26, 2022 - wife filed her MFNT, a notice of appeal, and a request for findings of fact and conclusions of law.
- MFNT was overruled by operation of law.
- September 28, 2022 -the trial court signed Findings of Fact and Conclusions of Law.

Issue #1 on Appeal

1. Did the trial court err by failing to grant a new trial after an allegedly significant change in the law relating to the procedures by which the case was tried

   -Wife argues embryos are "children," not property, and subject to the Family Code provisions regarding child custody and gestational agreements, relying on Texas Health and Safety Code Section 170A.001(5), which became effective with the *Dobbs* decision.

   -Appellate court holds Dobbs is not “applicable law” to this case.

Definitions under Texas Human Life Protection Act

- Section 170A.001(5) defines an "unborn child" as:
  - "an individual living member of the homo sapiens species from fertilization until birth, including the entire embryonic and fetal stages of development."

Definitions under Texas Human Life Protection Act

Section 170A.001(1) defines "abortion" as defined by Texas Health and Safety Code Section 245.002, which provides

(1) "Abortion" means the act of using or prescribing an instrument, a drug, a medicine, or any other substance, device, or means with the intent **to cause the death of an unborn child of a woman known to be pregnant**. The term does not include birth control devices or oral contraceptives. An act is not an abortion if the act is done with the intent to:'

(A) save the life or preserve the health of an unborn child;

(B) remove a dead, unborn child whose death was caused by spontaneous abortion; or

(C) remove an ectopic pregnancy

"Pregnant" is defined as "the female human reproductive condition of **having a living unborn child within the female's body during the entire embryonic and fetal stages of the unborn child's development from fertilization until birth**." Tex. Health &Safety Code Ann. § 170A.001(3) (Emphasis added)

Texas Penal Code & Tex. Civ. Prac & Rem

- Act providing criminal penalties and civil remedies "for death or injury to an unborn child." Act of May 31, 2003, ch. 822, 2003 Tex. Gen. Laws 2607.

- Texas Penal Code 1.07(a)(26) defines "individual" as "a human being who is alive, including an unborn child *at every stage of gestation* from fertilization until birth." (emphasis added).

- Tex. Civ. Prac & Rem. Code 71.001(4) "individual includes an unborn child *at every stage of gestation* from fertilization until birth. (emphasis added).

- Appellate court states:

Wife admits in her brief that "IVF embryos, prior to being implanted are not gestating. Thus, we do not construe the Penal Code definition of an "individual" to include fertilized embryos cryogenically preserved outside a woman's body. A similar conclusion would arguably be reached under the wrongful death statute which defines an "individual" to include "an unborn child at every stage of gestation from fertilization until birth." Tex. Civ. Prac. & Rem. Code Ann. § 71.001(4)

Issues #2 and #3

2. whether the trial court erred by treating the embryos as property;

3. whether there was "privity of contract" between husband and wife for purposes of making the contractual agreement between the couple and the IVF clinic separately binding between the husband and the wife;

Issues #2 and #3

- Trial court did not abuse its discretion in treating the embryos as property subject to contractual rights.
- Appellate court relies on persuasive authority of *Roman v. Roman*, 193 S.W.3d 40, 54-55 (Tex. App.-Houston [1st Dist.] 2006, pet. denied).
- Elements required for a valid and binding contract (in addition to consideration): (1) an offer, (2) acceptance in strict compliance with the terms of the offer, (3) a meeting of the minds, (4) each party's consent to the terms, and (5) execution and delivery of the contract with the intent that it be mutual and binding.
- Held:

Roman v. Roman

- Appellate court's discussion of Roman v. Roman:
  - No post-*Roman* Texas cases deciding the issue.
  - "Prior to *Roman*, Texas legislature enacted laws related to assisted reproduction and gestational agreements, but it had not, and has not since, addressed the legal status of frozen embryos or the rights to ownership or possession of frozen embryos upon the divorce of the parties creating the frozen embryos. We are persuaded that the legislature's failure to address the holding in *Roman* indicates its acquiescence in its holding."

Issue #4

- In issue four, wife questions whether the trial court terminated the "parental rights" of wife regarding the embryos in violation of the Family Code and without sufficient due process of the law.
  - Same basis of arguing embryos are “unborn children”
  - Appellate court overrules fourth issue on same grounds as earlier points.

Petition to Texas Supreme Court

- Petition for review filed Sept. 7, 2023
- Multiple amicus briefs filed

ASRM Amicus Brief

- Discusses how a decision in favor of petitioner could upend IVF in Texas.
- Responds to legal arguments

Where are we now?

- Petition denied on June 14, 2024
- Legislative session begins on January 15, 2025

AI in Healthcare: Examining the Matrix of Risk & Opportunities

Bradley E. Byrne Jr., Esq.

ProAssurance
Treated Fairly

Disclaimer

The information provided in this presentation offers risk management strategies and resources, and the slide content is intended to be used only with the accompanying oral presentation.

Guidance and recommendations contained in this presentation are not intended to determine the standard of care but are provided as risk management advice only. The ultimate judgment regarding the propriety of any method of care must be made by the healthcare professional.

The information does not constitute a legal opinion, nor is it a substitute for legal advice. Legal inquiries about this topic should be directed to an attorney.

Faculty

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Birmingham, Alabama

What Is Artificial Intelligence (AI)?

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Development of AI

- 1950s

Artificial Intelligence

- First AI program developed in 1955

- 1980s

Machine Learning

- Machine learning begins to flourish
- Requires human intervention

- 2010s

Deep Learning

- AI boom driven by breakthroughs in deep learning
- Does not require human intervention

Datasets

Public

Private

Synthetic

Datasets in Healthcare

EHR

Clinical trial data

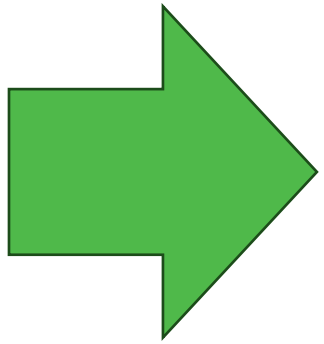
Genetic data

Wearable device data

Imaging data

Impact of AI on Healthcare

- Diagnoses
- Treatment
- Staffing Issues
- Research and Development
- Patient Experience



Size of AI Healthcare Market

- $11B (2021)
- $187B (2030)

Higher Education – AI in Healthcare Degrees/Certificates

Current Implementation

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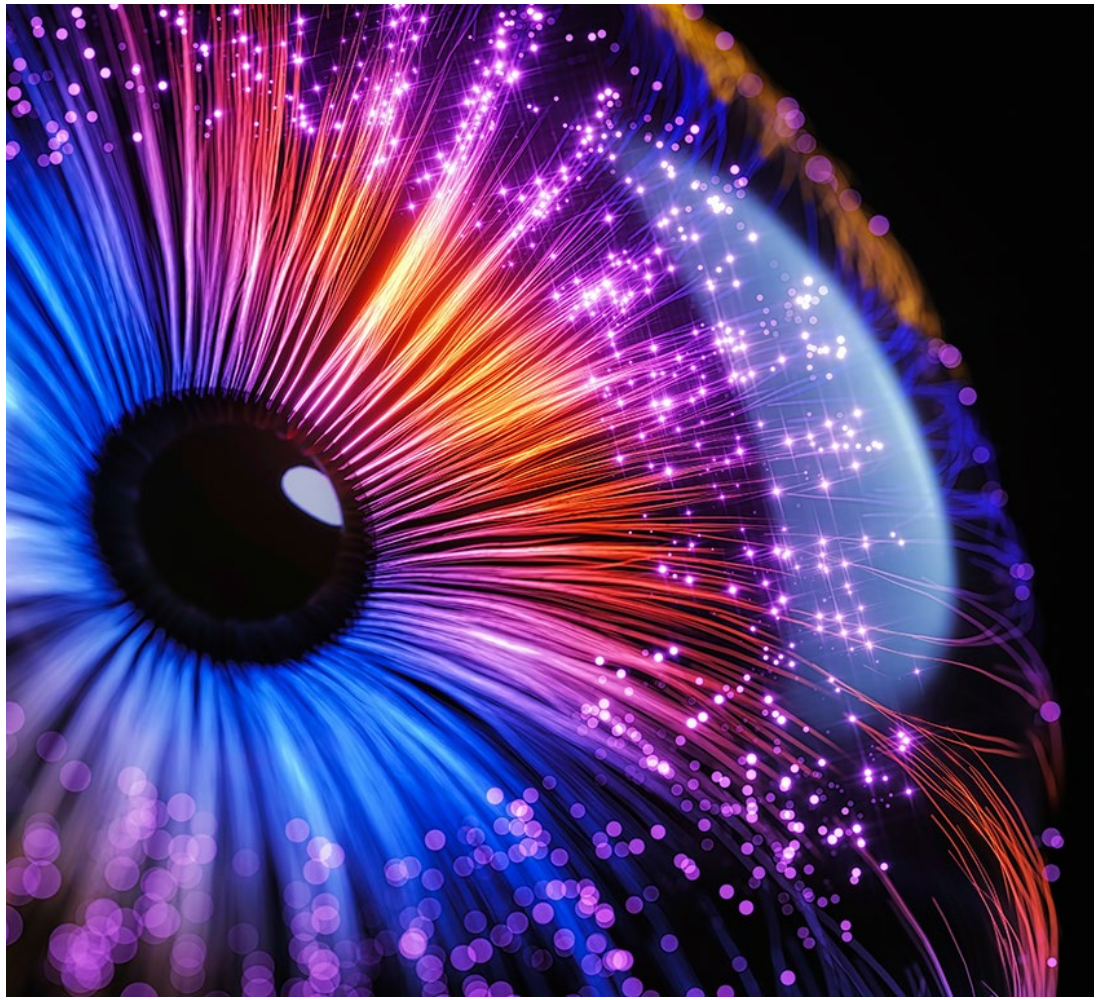
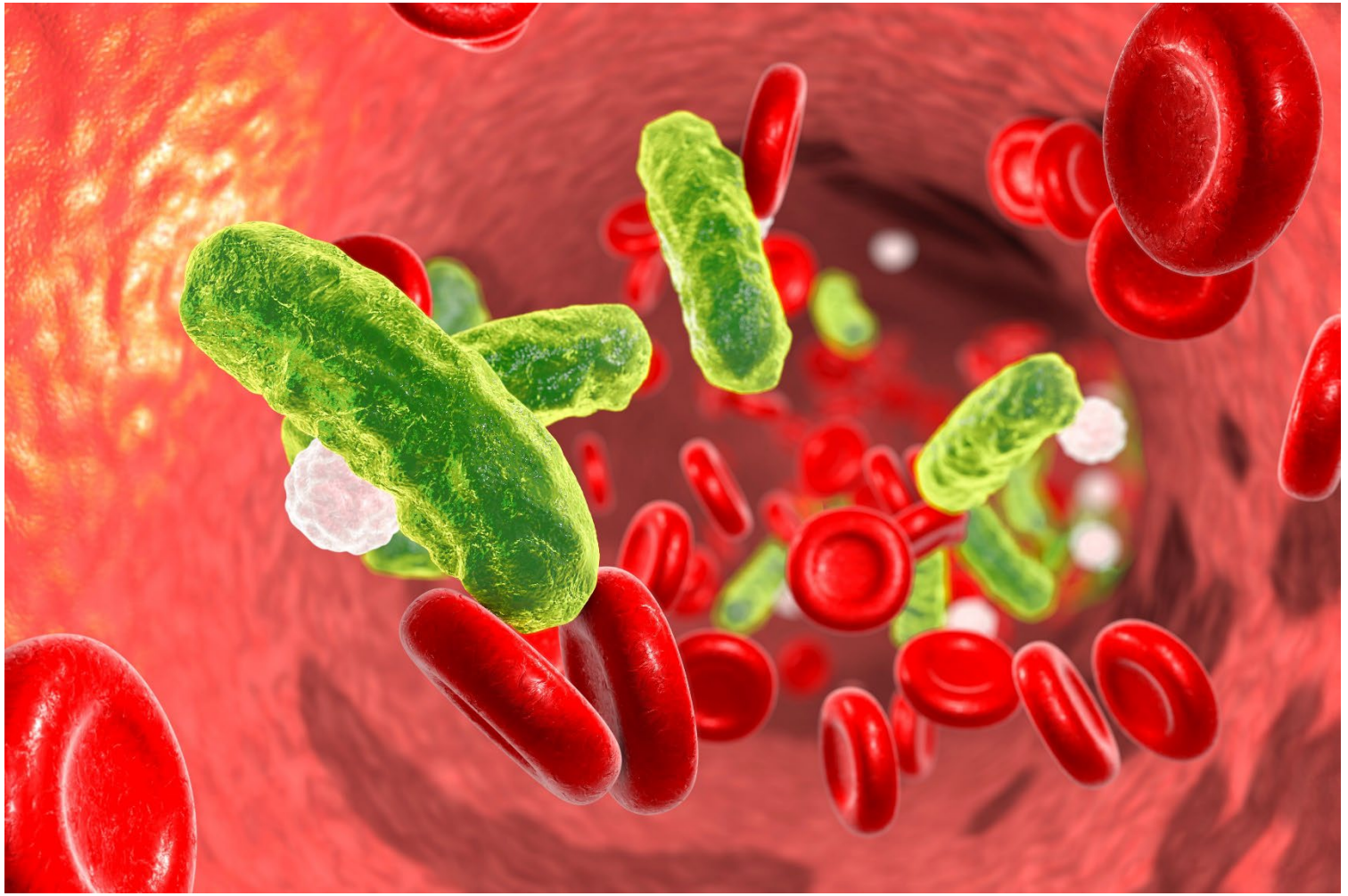
AI Utilization - Addressing Common Conditions



Early Diabetic Retinopathy Diagnosis

AI Utilization - Addressing Common Conditions

Sepsis Diagnosis



AI Utilization - Addressing Common Conditions

Prediction of Unfavorable Outcomes During Intrapartum Period

AI – Enhancing Breast Cancer Detection

- AI-supported results were similar to standard double reads
- Conclusion - AI considered safe

"I think of AI as more validation. It doesn't sleep. AI doesn't get tired. The AI doesn't get fatigued…"

Dr. Laura Heacock, a breast radiologist
at NYU Langone Perlmutter Cancer Center

Potential Liabilities & Regulatory Framework

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Current Regulatory Framework

AI Regulation

- 2019 - Executive Order 13859
- 2020 - AI in Government Act of 2020 & Executive Order 13960
- 2023 - FDA Guidance for AI/ML-Based SaMD
- 2023 - Executive Order

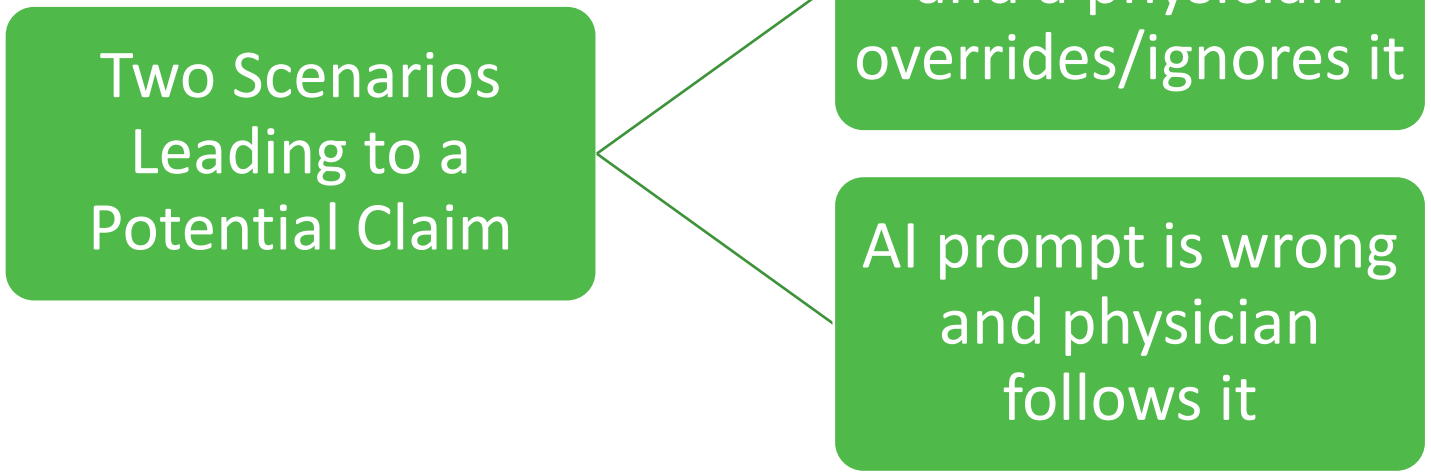
AI Healthcare Regulation

- Federal/State
- American Medical Association efforts

Theories of Legal Liability

- Professional Negligence
- Product Liability
- Breach of Contract
- Fraud
- Invasion of Privacy

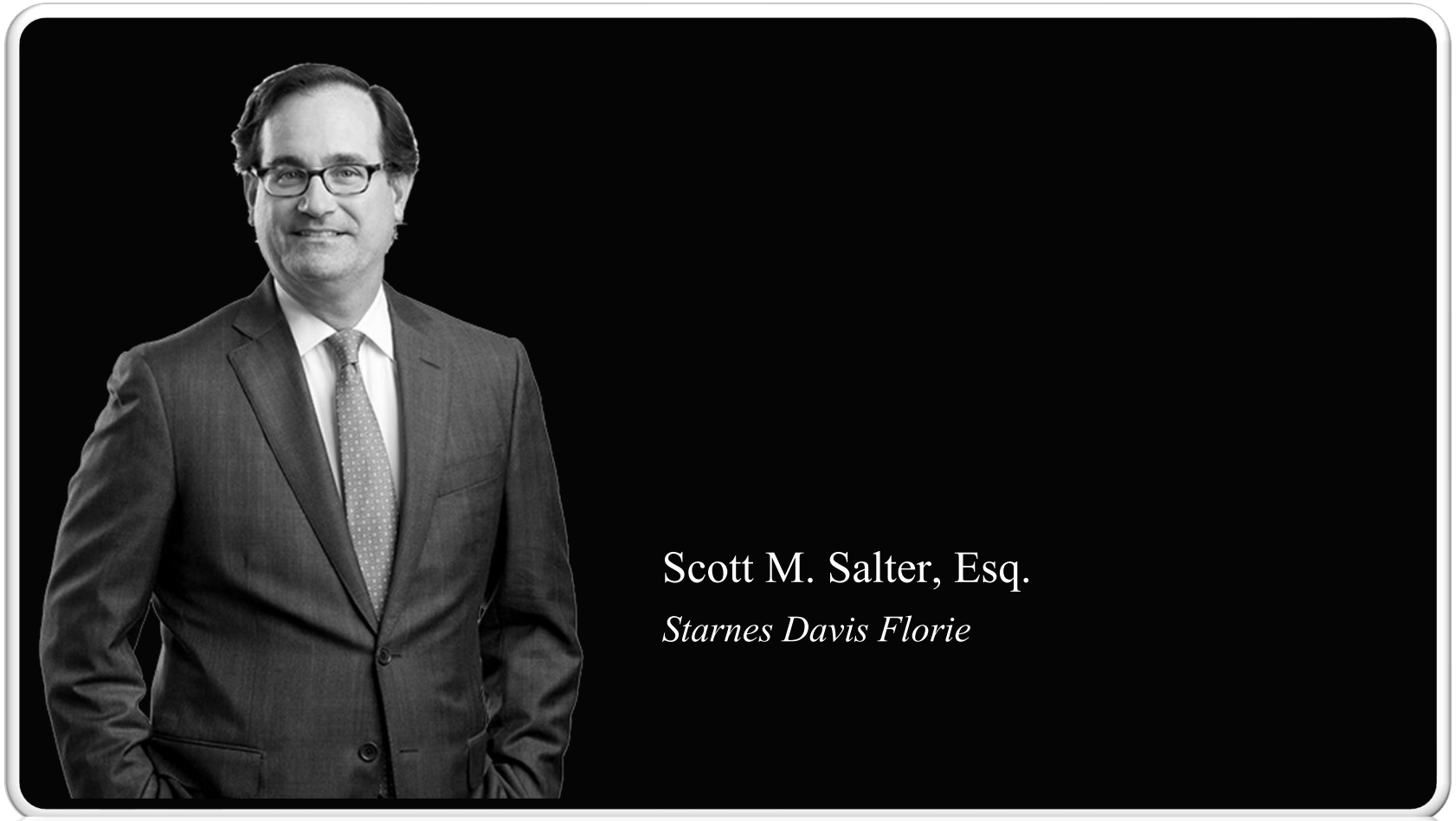
Professional Negligence



"…[t]he ultimate responsibility for a diagnostic or therapeutic decision will likely remain with the physician, who has to validate the results of the CDS [clinical decision support] tool."

Hedderich, D.M., Weisstanner, C., Van Cauter, S. *et al.* Artificial intelligence tools in clinical neuroradiology: essential medico-legal aspects. *Neuroradiology* **65**, 1091–1099 (2023). https://doi.org/10.1007/s00234-023-03152-7

AI & Standard of Care



Biased Data in Healthcare AI – 2019 Landmark Study

- Hospital AI algorithm used to predict high-risk care management needs.
- Past cost data was used to determine risk.
- Unequal access to care for Black patients resulted in less money spent on their care.
- The need for healthcare ≠ prior healthcare costs.
- The AI discriminated against Black patients by assigning lower risk scores.

Obstacles to Eliminating Bias

We have work to do:

- Easy to miss embedded biases, even when you're looking for them
- Racial biases in AI will perpetuate

Researchers warn:

"AI-driven tools have the potential to codify bias in healthcare settings"

ACA Section 1557

- Covered entities must not discriminate on the basis of race, color, national origin, sex, age, or disability through the use of clinical algorithms in its decision-making

Litigation Involving AI

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Health Insurance Claims Reviews

Allegation: Class action case alleging a national health insurance company's use of AI to review medical necessity of submitted claims violated mandatory rules and improperly denied claims.

Plaintiffs allege that, per California insurance law, "medically necessary" reviews of claims must be thorough, fair, and objective.

Plaintiffs allege the law requires that individual physicians review each claim separately to approve or deny claims.

Plaintiffs allege the insurer's use of the AI's algorithm to look for discrepancies unfairly denies claims without genuine investigation, as the physicians simply sign off on the denials.

Case is pending.

Suzanne Kisting-Leung, et al. v. Cigna Corporation, et al. No. 22-cv-03031 (E.D. CA.)
filed July 24, 2023

HIPAA & AI

Allegation: Google and the University of Chicago Medical Center disclosed PHI when they supplied medical records to AI system.

As part of a research collaboration between the University of Chicago Medical Center and Google, the University gave Google anonymized patient medical records to implement AI-driven predictive health models.

Former patient sued Google and the University, alleging violation of HIPAA, among other causes of action.

The district court dismissed the case.

The Seventh Circuit affirmed the dismissal.

Dinerstein v. Google, LLC, 73 F.4th 502 (7th Cir. 2023)

What is on the Legal Horizon?

- Predictive models will be scrutinized
- Privacy claims will be common
- Plaintiffs will be creative

Risk Reduction

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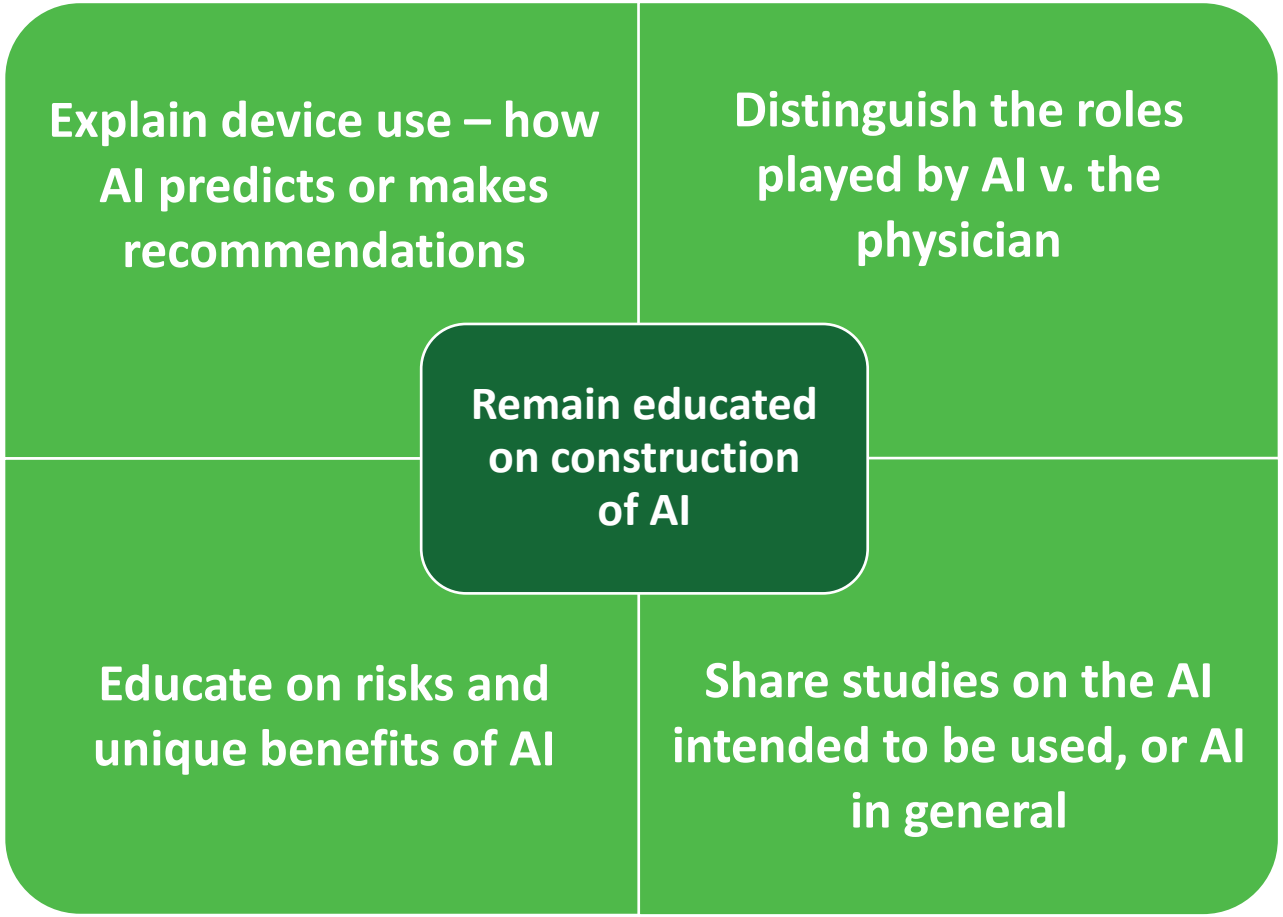
Risk Reduction Strategies

Maintain Knowledge of Your AI Products/Services

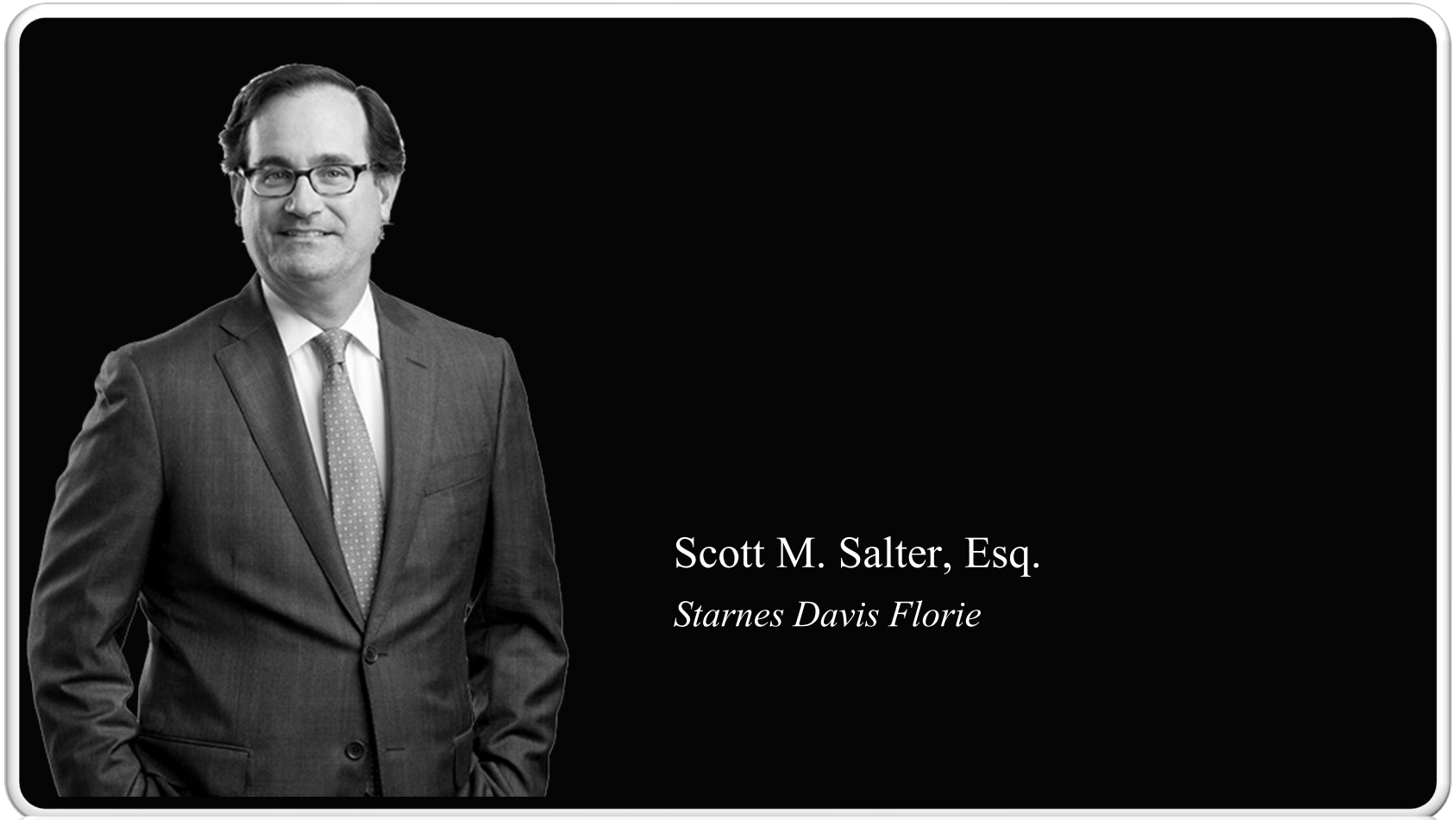
1. Avoid Wearing Blinders
2. Train Staff
3. Ensure Data Quality
4. Stay Informed/ Proactive
5. Lean into AI's Benefits

Risk Reduction Strategies - Informed Consent

AMA Journal of Ethics



Risk Reduction Strategies - AI & Informed Consent



Follow the Standard of Care (SOC)

Use AI for Its Intended Use

Keep Up with Any Changes in SOC

Train Staff on the Application of AI

Use AI as a Resource in the Toolbox

Looking Forward…

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AI – Confidence or Doubt?

- 60% of American adults were uncomfortable with reliance on AI
- 33% of American adults thought AI would lead to worse health outcomes
- 75% were worried their healthcare providers would adopt AI too quickly, without full contemplation of risks

Final Thoughts

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THANK YOU

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