



## Case of the Month



### How Incomplete Consent Led to an Indefensible Case

by Brad Dunkin, MHA

This *Case of the Month* involves a patient's death following aortic surgery<sup>1</sup> and highlights the importance of informed consent and documentation before high-risk procedures.

If certain actions had been taken, the patient's death and resulting medical malpractice lawsuit could have possibly been avoided.

A 73-year-old male patient was referred to a vascular surgeon by his primary care physician. The patient suffered from exertional leg pain that tended to subside with rest and reported that he experienced more pain in his right leg compared to the left leg. A review of the patient's medical record revealed he had a history of smoking, hypertension, hyperlipidemia, and medically managed coronary artery disease. Despite this history, the patient did not report any chest pain.

The surgeon noted that the patient was "absent a right femoral pulse, a diminished left femoral pulse, and no palpable pulses in the feet. The skin was pink without evidence of tissue loss. Noninvasive studies confirmed arterial occlusive disease bilaterally, worse on the right. A diagnostic arteriogram showed severe aortoiliac occlusive disease, with 'coral reef-like projections' at the aortic bifurcation and occlusion of the right common iliac artery."<sup>1</sup>

At the conclusion of the patient examination, the surgeon recommended extra-anatomic bypass and aortobifemoral bypass as viable surgeries for the patient. Extra-anatomic bypass may involve bypassing arteries in different parts of the body, while aortobifemoral bypass specifically targets blockages in the aorta and femoral arteries in the legs. After reviewing these options, the patient agreed to undergo an aortobifemoral bypass.

Upon review of the informed consent discussion with the patient, there was minimal information presented about the risks of aortobifemoral bypass for a patient with a history of coronary artery disease. Additionally, there was no discussion of alternative treatment, i.e., less invasive endovascular procedures. The surgeon scheduled the patient for surgery without ordering any preoperative clearance.

On the morning of the surgery two weeks later, the surgeon encountered serious complications. The patient's aorta was significantly calcified, which hindered the surgeon's efforts to place a clamp on it. The surgeon attempted to rectify the situation with an intraluminal balloon catheter, but the balloon ruptured after it was inflated. As a result, the patient experienced a hemorrhage and went into cardiac arrest, requiring resuscitation efforts. Although bleeding was briefly

controlled, the surgeon's attempt to place a prosthetic graft was unsuccessful given the patient's tearing in the aorta adventitia. The patient arrested again, however, resuscitation attempts failed and the patient died. The official cause of death was acute abdominal hemorrhage. An autopsy of the patient also revealed significant stenosis of the coronary arteries.

The patient's family sued the vascular surgeon. Several significant issues were identified by both plaintiff and defense experts, which made this case extremely difficult to defend. The experts' reviews revealed a troubling pattern leading up to the surgery and the subsequent surgery itself:

1. Informed consent discussions and processes indicated a lack of attention to alternative interventions, primarily consideration of endovascular procedures.
2. There was no preoperative clearance obtained on the patient.
3. The patient did not have limb-threatening ischemia, raising questions about the need for the procedure in the first place.
4. When the surgeon encountered difficulty clamping the aorta, the surgery should have been halted.
5. The presence of atheromatous plaque was contraindicated to the balloon placement which ultimately ruptured.
6. In general, sharp criticisms were made regarding the surgeon's decision-making and rationale preoperatively and during the surgery.
7. Lastly, documentation became a significant distraction. A review of the medical record revealed the patient's admission history and physical exam did not take place until two months after the patient's death.

The claim was settled prior to trial.

There were several junctures, prior to, during, and after the surgery where certain steps could have been taken to avoid this tragic and indefensible outcome.

A glaring flaw from the start was the lack of a well-executed informed process. This is an ongoing issue with many medical malpractice cases today and continues to be an area of needed attention.

To avoid the allegations that are associated with improper or incomplete informed consent, the Cooperative of American Physicians (CAP) recommends the following based on historical case precedent and best practices:<sup>2</sup>

- Explanation of the nature and purpose of the proposed treatment, including:
  - The risks, complications, and expected benefits of the recommended treatment, along with the likelihood of success or failure.
  - Any alternatives to the recommended treatment and their risks and benefits.
  - The risks and benefits of declining the proposed treatment.
- For planned procedures, do not wait to obtain consent on the day of the procedure. The informed consent process should begin as early as two weeks prior to the planned procedure, preferably in the provider's office setting. This allows enough time for the patient and physician to have a detailed discussion and to answer all the patient's questions in a stress-free setting as opposed to a preoperative holding area.
- Thoroughly document the informed consent discussion and be sure to include all the previously mentioned elements. Also be sure to include any pertinent questions that the patient had, and what answer was provided.

- Do not just rely on the language in a standardized or general consent form. Your documentation of the informed consent conversation and the potential risks should be specific to the procedure being performed.
- Ensure that the copy of the signed consent form is placed in the patient's medical record, and a copy is added to the hospital record as well if the procedure takes place in a hospital setting.
- Stay within the scope of the procedure noted on the signed consent form. Outside of an emergent life-threatening occurrence that would require the physician to take immediate life-saving measures, do not be tempted to "fix other problems" you might encounter intraoperatively.<sup>2</sup>

Today, evidence of a thorough informed consent process and discussion is critical for defending a medical malpractice case. A comprehensive informed consent process should empower patients to make decisions about their healthcare, ensuring that they have a full understanding of the risks, benefits, and alternatives associated with a particular procedure or treatment. It is important for healthcare providers to take the time to fully explain all relevant information to patients and answer any questions they may have to facilitate a truly informed decision-making process.

Unfortunately, in this case, alternative less invasive or risky interventions were not presented by the surgeon or discussed with the patient as part of a well-executed informed consent process. Specifically, the surgeon failed the patient by not discussing and documenting alternatives to the aortobifemoral bypass, such as endovascular intervention or medical management.

Lack of documentation of the surgeon's rationale for the procedure and the patient's admission history led to complications and became a major issue after the patient's death.

Defense attorneys rely on complete and timely documentation with respect to patient medical records. Deficiencies in documentation detract from the validity and integrity of the care rendered to the patient. A defense attorney mantra is "do not let documentation become a distraction" in a medical malpractice case.

This case highlighted many key issues that unfortunately resulted in the death of a patient, the ultimate adverse event. The takeaway is that diligent incorporation of risk management strategies, notably properly executed informed consent, are designed to improve patient outcomes, reduce malpractice claims, and navigate a medical malpractice claim more successfully.

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<sup>1</sup>David Han, MD, FACS, and Jacqueline Ross, RN, PhD. "Lessons Learned from a Medical Malpractice Lawsuit: Aortic Surgery in a Patient with Significant Underlying Coronary Disease." American College of Surgeons. January 2025.

<sup>2</sup>Dunkin, Bradford S., MHA. "The Critical Link Between Informed Consent, Thorough Documentation, and Effective Defense of Medical Care." Cooperative of American Physicians. January 2025. <https://www.capphysicians.com/articles/critical-link-between-informed-consent-thorough-documentation-and-effective-defense>

# RISK MANAGEMENT AND PATIENT SAFETY NEWS



## COVID Vaccine Recommendations: What Physicians Should Know

by Deanna Spounias, Pharm.D.

COVID-19 vaccine recommendations are rapidly shifting. Physicians and their staff should have the latest information addressing common questions about the differences in COVID-19 vaccine recommendations, the expiration of the COVID vaccine Emergency Use Authorization (EUA) by the Food and Drug Administration (FDA), the protections offered under the Public Readiness and Emergency Preparedness (PREP) Act going forward, and the differences between guidelines provided by the American Academy of Pediatrics (AAP), American Academy of Family Physicians (AAFP), and the Centers for Disease Control and Prevention (CDC).

The California Department of Public Health (CDPH) continues to recommend that everyone aged 6 months and older have access to the vaccine and the choice to receive COVID-19 vaccines. Groups at higher risk of severe illness should receive protection.<sup>1</sup> These groups include infants and toddlers, pregnant people, older adults, and others with risks of serious disease. The CDPH is working with partners, including the West Coast Health Alliance, to continue promoting vaccine access and provide science and fact-based information on vaccine safety and efficacy.

More information and resources are available at:  
**West Coast Health Alliance:** <https://www.gov.ca.gov/2025/09/03/california-oregon-and-washington-to-launch-new-west-coast-health-alliance->

[to-uphold-scientific-integrity-in-public-health-as-trump-destroys-cdcs-credibility/](#)

**CDPH:** <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Immunization/ncov2019.aspx>

**Q: The Covid-19 vaccine(s) emergency use authorization(s) have expired; how does this impact my liability?**

On December 11, 2024, Health and Human Services (HHS) Secretary Xavier Becerra signed the 12th amendment to the PREP Act, extending its protections through December 31, 2029. The PREP Act went into effect January 1, 2025.<sup>2</sup>

- The PREP Act extension maintains liability immunity for providers administering COVID-19 vaccines and other covered countermeasures, regardless of whether the vaccine is administered under CDC or AAP/AAFP guidance. Immunity includes claims for: death; physical, mental, or emotional injury, illness, disability, or condition or fear of any such injury, illness, disability, or condition; any need for medical monitoring; or property damage or loss, including business interruption loss.<sup>3</sup>

**NOTE:** *The only exception to liability immunity under the PREP Act is a claim for willful misconduct, which is defined in the PREP Act as an act or omission that is taken (i) intentionally to achieve a wrongful purpose; (ii) knowingly without legal or factual*

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justification; and (iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit. The PREP Act specifies that criteria for willful misconduct must be construed to establish a standard for liability that is more stringent than a standard of negligence in any form or recklessness.<sup>3</sup>

The amendment does not address or alter the scope of immunity based on differences in clinical recommendations between the CDC and AAP/AAFP.

**Q: What are the implications of the PREP Act for those who immunize infants and children?**

Physicians who follow AAP or AAFP recommendations—even if they differ from CDC guidance—are still covered under the PREP Act as long as the vaccine is FDA authorized, licensed, or approved and administered during the declared public health emergency period.<sup>3</sup>

**Q: What are the key differences between the new guidelines for COVID-19 vaccination for infants and children between 6 months and 23 months old?**

The key distinctions between the recommendations from the AAP, AAFP, and the CDC rest on the language between should receive, should be, and shared clinical decision-making, as follows:

- **AAP Guidance:** The AAP recommends that infants and children aged 6 through 23 months should—who do not have contraindications—receive the 2025–2026 COVID-19 vaccine. Their guidance includes specific recommendations based on vaccination status and risk categories.<sup>4</sup>
- **AAFP Guidance:** The AAFP recommends all children ages 6–23 months should be vaccinated against COVID-19 and use a risk-based single dose approach for children and teens 2–18 years.<sup>5</sup>
- **CDC Guidance:** The CDC’s updated guidance for individuals aged 6 months to 17 years who are not moderately or severely immunocompromised emphasizes shared clinical decision-making. This approach encourages healthcare providers to engage with patients and their families to make individualized vaccination decisions based on personal preferences and circumstances.<sup>6</sup>
- **CDPH Guidance:** The CDPH recommends vaccinations for COVID-19 for infants and toddlers aged 6 months to 23 months.<sup>1</sup>

The AAP Immunization Schedule can be found at <https://publications.aap.org/redbook/resources/15585/AAP-Immunization-Schedule>.

The Child and Adolescent Immunization Schedule, published by the CDC, which is not currently endorsed by the AAP, can be found at <https://www.cdc.gov/vaccines/hcp/imz-schedules/downloads/child/0-18yrs-child-combined-schedule.pdf>.

**Q: Does CAP recommend one guideline over the other for their members?**

- No, CAP does not endorse one guideline over the other and recommends that practices follow either AAP, AAFP or CDC guidance and clearly document which guideline is being followed.
  - Moreover, if more than one (1) set of guidelines is discussed with the parent(s)/caregiver, document which guidelines were discussed.
  - These principles can apply to administration of any vaccine, not only COVID-19 vaccinations.
- The decision regarding which guideline to adopt rests with the physician.



**Q: Does CAP provide a specialized vaccination consent form for their members?**

No, CAP does not currently provide specialized vaccination consent forms, as a standard consent form is sufficient. It is important to note that no consent form can fully eliminate liability or risk and that forms are only an adjunct to a proper informed consent discussion.

*NOTE: California Department of Public Health (CDPH) Guidance—There are no federal or California state requirements for informed consent specifically relating to immunization. Federal law requires that healthcare staff provide a Vaccine Information Statement (VIS) to a patient, parent, or legal representative before each dose of certain vaccines.<sup>7</sup>*

**Q: What if I have a parent/caregiver/guardian who wants to receive a vaccination at the time of the visit with their child in my pediatric practice?**

- If your pediatric practice elects to vaccinate parents, caregivers, or guardians, the physician must follow standard intake/immunization procedures.
- This includes, but is not limited to, documenting allergies, past medical history, obtaining informed consent or refusal, providing a VIS, and offering appropriate aftercare instructions.

- Documentation for immunizations given to these individuals should be maintained in a separate, “confidential” section of the child’s medical record
- Guidelines on this topic published by the AAP can be found at <https://publications.aap.org/pediatrics/article/129/1/e247/31548/Immunizing-Parents-and-Other-Close-Family-Contacts>. The AAP reaffirmed this technical report in November 2024.

**Legal Disclaimer:** The information provided herein is for general guidance only and does not constitute legal advice. Also note: While the PREP Act offers broad liability protections for providers administering COVID-19 vaccines, practices should consult legal counsel and review their malpractice liability coverage to ensure compliance with federal and state regulations. Differences in clinical guidance between the AAP and CDC do not affect the scope of PREP Act immunity, provided vaccines are administered in accordance with FDA authorization and applicable public health declarations.<sup>8</sup> ➔

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<sup>1</sup>California Department of Public Health. *Populations at Increased Risk Recommended for Vaccination Against COVID-19*. September 2025. <https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/Immunization/populations-at-risk-covid.pdf>

<sup>2</sup>American Association of Colleges of Osteopathic Medicine (AACOM). *HHS Secretary Extends PREP Act for COVID-19*. December 16, 2024. <https://www.aacom.org/news-reports/news/2024/12/16/hhs-secretary-extends-prep-act-for-covid-19>

<sup>3</sup>U.S. Department of Health & Human Services, Administration for Strategic Preparedness and Response (ASPR). *PREP Act Question and Answers*. <https://aspr.hhs.gov/legal/PREPAct/Pages/PREP-Act-Question-and-Answers.aspx>

<sup>4</sup>American Academy of Pediatrics, Committee on Infectious Diseases. *Recommendations for COVID-19 Vaccines in Infants, Children, and Adolescents: Policy Statement*. *Pediatrics*, 156(5), e2025073924. November 2025. <https://doi.org/10.1542/peds.2025-073924>

<sup>5</sup>American Academy of Family Physicians. *Immunizations & Vaccines*. <https://www.aafp.org/family-physician/patient-care/prevention-wellness/immunizations-vaccines.html>

<sup>6</sup>Centers for Disease Control and Prevention. *Staying Up to Date with COVID-19 Vaccines*. November 19, 2025. <https://www.cdc.gov/covid/vaccines/stay-up-to-date.html>

<sup>7</sup>California Department of Public Health. *Laws and Regulations*. <https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Immunization/laws.aspx>

<sup>8</sup>U.S. Department of Health & Human Services, Administration for Strategic Preparedness and Response. *Public Readiness and Emergency Preparedness (PREP) Act*. <https://aspr.hhs.gov/legal/PREPAct/Pages/default.aspx>



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*Andie Tena is Assistant Vice President, Practice Management Services. Questions or comments related to this column should be directed to ATena@CAPphysicians.com.*

## New Healthcare Laws in 2026: Key Takeaways for Practicing Physicians

by Gabriela Villanueva

During the 2025 legislative session, Governor Gavin Newsom signed 794 bills into law and vetoed 123 bills.<sup>1</sup> New healthcare-related laws, effective January 1, 2026, focus on increased regulatory oversight of healthcare transactions, limits on corporate influence, prescription drug cost controls, and guardrails on the use of artificial intelligence (AI) in clinical settings.

### Increased Oversight of Healthcare Transactions

**Assembly Bill 1415** — Expanded Authority of the Office of Health Care Affordability

*Author: Assemblymember Mia Bonta (D-Oakland)*

AB 1415 significantly expands the authority of the

Office of Health Care Affordability (OHCA) to review healthcare transactions involving physician groups, hospitals, management services organizations (MSOs), and private equity investors.

The law broadens reporting and advance notice requirements for material transactions, including practice acquisitions, consolidations, and certain contracting arrangements. OHCA is empowered to analyze the impact of these transactions on healthcare costs, access, and quality.

Practices considering mergers, acquisitions, or MSO arrangements may face additional disclosure



and review requirements and transactions may be delayed or subject to increased scrutiny, particularly those involving investor-backed entities.

**Senate Bill 351** — Strengthening Corporate Practice of Medicine Protections

*Author: Senator Christopher Cabaldon (D–Napa)*

SB 351 codifies and enhances California’s corporate practice of medicine restrictions for the first time with clear statutory language, explicitly limiting the control that private equity firms and other non-clinical entities may exercise over medical and dental practices.

The law prohibits non-physician owners or investors from interfering in clinical decision-making, billing, staffing, compensation models tied to clinical judgment, or professional autonomy. It also voids contract provisions that restrict physicians from reporting quality-of-care concerns or competing after leaving a practice.

Enforcement authority will lie with the California Attorney General. Existing MSO and private equity-backed contracts may need to be reviewed and amended with the purpose of having physicians gain clearer statutory protections for clinical independence.

**Prescription Drug Cost Regulations**

**Senate Bill 40** — Insulin Cost-Sharing Limits

*Author: Senator Scott Wiener (D–San Francisco)*

SB 40 places a cap on insulin cost-sharing for large group health plans, limiting copayments, deductibles, and coinsurance to no more than \$35 for a 30-day supply starting January 1, 2026 (with a similar cap for small and individual plans beginning in 2027). It also restricts step therapy requirements and ensures that at least one form of each type of insulin is on the formulary.

**Senate Bill 41** — Pharmacy Benefit Manager (PBM) Oversight

*Author: Senator Scott Wiener (D–San Francisco)*

SB 41 imposes new regulatory standards on pharmacy benefit managers, addressing pricing practices, conflicts of interest, and transparency. While implementation details vary, the law is intended to reduce drug price inflation and improve reimbursement clarity. Potential downstream effects can provide for improved transparency and prepare for changes in drug pricing and patient affordability with changes in patient out-of-pocket costs over time.

**Artificial Intelligence and Clinical Communications**

**Assembly Bill 489** — Restrictions on AI Representing Clinical Authority

*Author: Assemblymember Mia Bonta (D–Oakland)*

AB 489 prohibits AI systems from presenting themselves as licensed healthcare professionals by using terms, titles, or phrasing that imply care or advice is being given by a licensed health professional when it is not. Any AI-generated health information must clearly disclose that it is not produced by a physician or other licensed clinician. Practices using AI tools (chatbots, triage systems, patient messaging platforms) must ensure proper disclosures to reduce risk of patient confusion or reliance on non-clinical advice. ➡

*Gabriela Villanueva is CAP’s Government and External Affairs Analyst. Questions or comments related to this article should be directed to [GVillanueva@CAPphysicians.com](mailto:GVillanueva@CAPphysicians.com).*

<sup>1</sup>Bollag, Sophia. "Here are 15 new laws that Californians must start following in 2026." San Francisco Chronicle. December 1, 2025. <https://www.sfchronicle.com/politics/article/new-california-laws-2026-21163923.php>.

# Understanding Cyber Risks in Healthcare: Why Protection Matters



Physicians handle vast amounts of sensitive patient data, making their practices prime targets for cyberattacks and data breaches. CyberRisk insurance helps cover the financial and legal consequences of these incidents, including HIPAA penalties, identity theft, and costs associated with restoring operations.

As data breaches are now more frequent and sophisticated than ever, it is important to purchase CyberRisk insurance to protect yourself, your patients, and your practice.

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CyberRisk insurance is available for purchase at excellent rates through Symphony Health, a division of Symphony Risk Solutions. Contact Symphony Health at 800-819-0061 or via email at [HealthCareServices@SymphonyRisk.com](mailto:HealthCareServices@SymphonyRisk.com) to learn more or request a free consultation.

## Important Reminder About Your Automatic CyberRisk Insurance Benefit

CAP members are reminded of the value-added insurance benefits CAP provides as part of their membership, including CyberRisk liability coverage. This cyberliability policy covers up to \$50,000 and 5,000 patient notifications per covered claim should you experience a data breach in your practice. CAP members should note that their CyberRisk benefit includes a \$2,500 deductible per covered claim.

In addition, your CyberRisk benefit is subject to a shared annual aggregate limit of \$10,000,000, which means that all amounts paid under CyberRisk on your behalf and on behalf of all other CAP members will reduce and may completely exhaust such shared annual aggregate limits. If the shared annual aggregate limit is exhausted, your individual CyberRisk limits will also be deemed exhausted, and there will be no further CyberRisk benefit available to you or others for the remainder of the year.

## Free Training for CAP Member Practices

To avoid potential claims, CAP encourages all member practices to implement strict cybersecurity measures. As part of the benefits of your CyberRisk coverage, you and your staff can access free HIPAA training courses on how to prevent data breaches, and much more at <https://CAP.nascybernet.com>.

First-time users will need to sign up for a free account with your CAP member number as your “Sign Up Code.” Once you have registered, you will be able to create usernames and passwords for your employees also.

## Easy Claims Handling

To report any claim or potential incident, please contact Tokio Marine HCC below, advise that you are a CAP member, and give your CAP member/entity number:

**Tokio Marine HCC - Cyber & Professional Lines Group**  
**Claims Department:** 16501 Ventura Blvd., Suite 200, Encino, CA 91436

**Claims Telephone Number:** 818-382-2030

**Claims Email Address:** [cpl.claims@tmhcc.com](mailto:cpl.claims@tmhcc.com)

There are no upfront costs to report a claim or potential claim. Tokio Marine HCC’s goal is to get you back up and running while reaching a successful resolution. When it comes to providing expert breach response, Tokio Marine HCC’s in-house claims team considers the needs of each member. ➦



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3. Practice administrators, select the course titled "The Successful Practice Manager." Physicians, select the course titled "The Successful Practice Manager – CME Version."
4. Click "Start" to begin. You can start and return anytime, but remember, the modules are in sequential order and cannot be viewed separately.

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