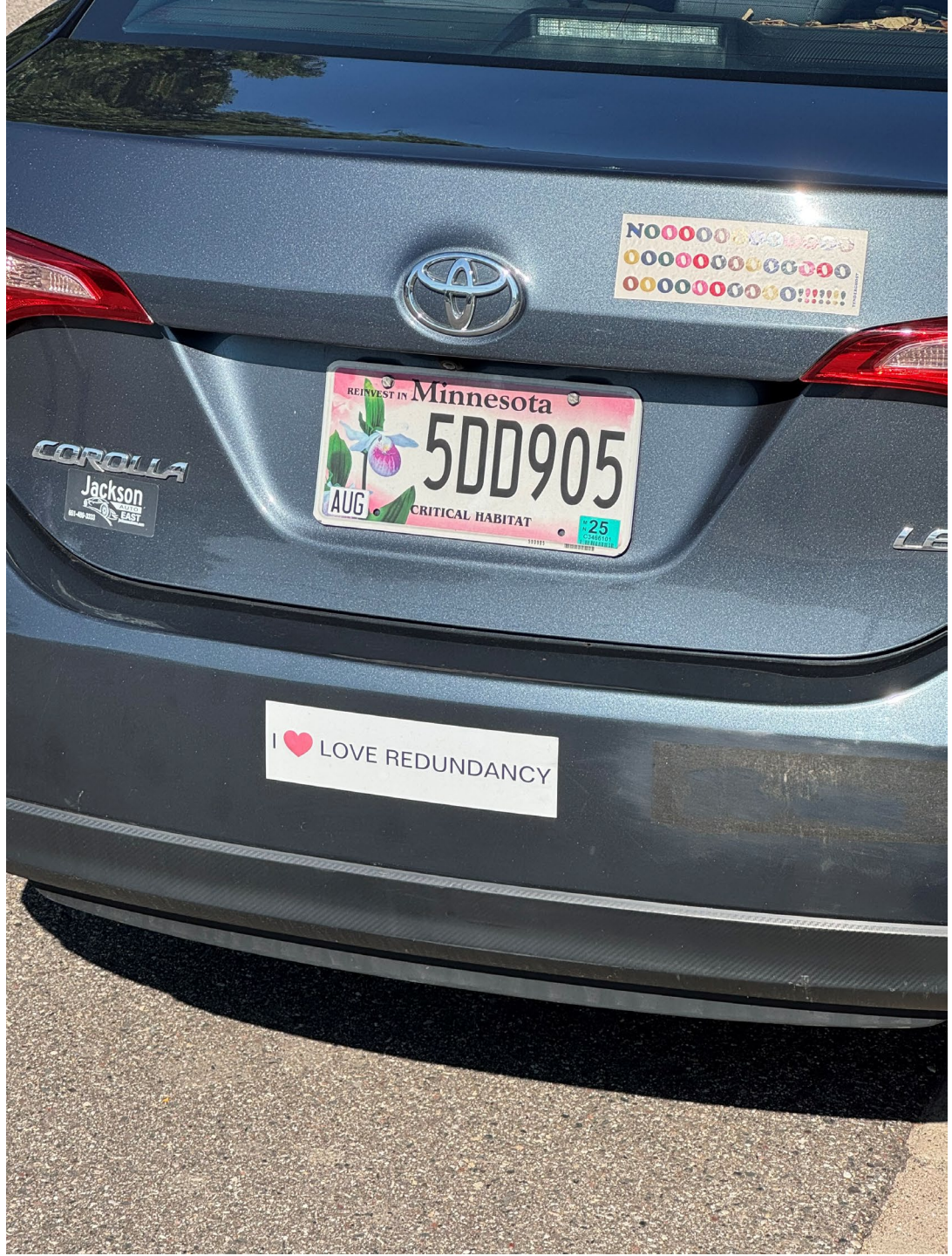
Health Law FAQ: Practical Answers to Common Questions

Health Law Webinar

August 13, 2025

Fredrikson



Fredrikson

A departed physician left unsigned notes. Should we refund or have someone else sign?

- Consider the payor: this may be a false choice.
- Medicare does not require signatures as a condition of payment (conditions of participation are different).
- What is the value of a different professional's signature?

Fredrikson

When do federal payors requires a physician co-signature for documentation or orders originating by a PA or Nurse Practitioner in a physician clinic setting? I understand each state has varying expectations, but what are the federal rules?

- The government doesn't totally know its own rules on this.
- There were no real signature requirements for PAYMENT until 42 CFR 410.20 and shared visits.
- October 31, 1997 FR confirms that only IDTF orders must be WRITTEN!
- That said, easier to sign than fight. Just don't refund off of missing signatures!

Fredrikson

For incident-to billing can the physician be “on-site” virtually?

- At least through 12/31, for Medicare, yes!
- Starting during the PHE supervision via audio/visual capability was allowed.
- Expires 12/31, but the proposed Medicare Fee fee schedule would make it “permanent.”

Fredrikson

Do we always bill under the supervising physician?

- For services billed incident-to, the supervising physician must be the billing physician for Medicare.
- For diagnostic tests like Xray and MRI (a separate benefit category and not performed “incident to”), Medicare manual language supports billing under either the ordering or supervising physician:
  - *If a diagnostic test (other than a clinical diagnostic laboratory test) is personally performed or is supervised by a physician, such physician may bill under the normal physician fee schedule rules. This includes situations in which the test is performed or supervised by another physician with whom the billing physician shares a practice.* See Medicare Claims Processing Manual, Section 20.3.1, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c13.pdf.

Fredrikson

Must a physician see the patient to bill a split/shared visit?

- No! You may think “doesn’t Medicare expect you to visualize the patient or some image of the patient?” But…
- CMS issued clear guidance:

> “For all split (or shared) visits, one of the practitioners must have face-to-face (in-person) contact with the patient, but it does not necessarily have to be the physician, nor the practitioner who performs the substantive portion and bills for the visit. The substantive portion can be entirely with or without direct patient contact, and is determined by the proportion of total time, not whether the time involves patient contact.”

Medicare Claims Processing Manual Chapter 12, 30.6.18 (B)(3)

Fredrikson

Is it a regulatory or legal requirement to treat everyone the same with respect to billing practices?

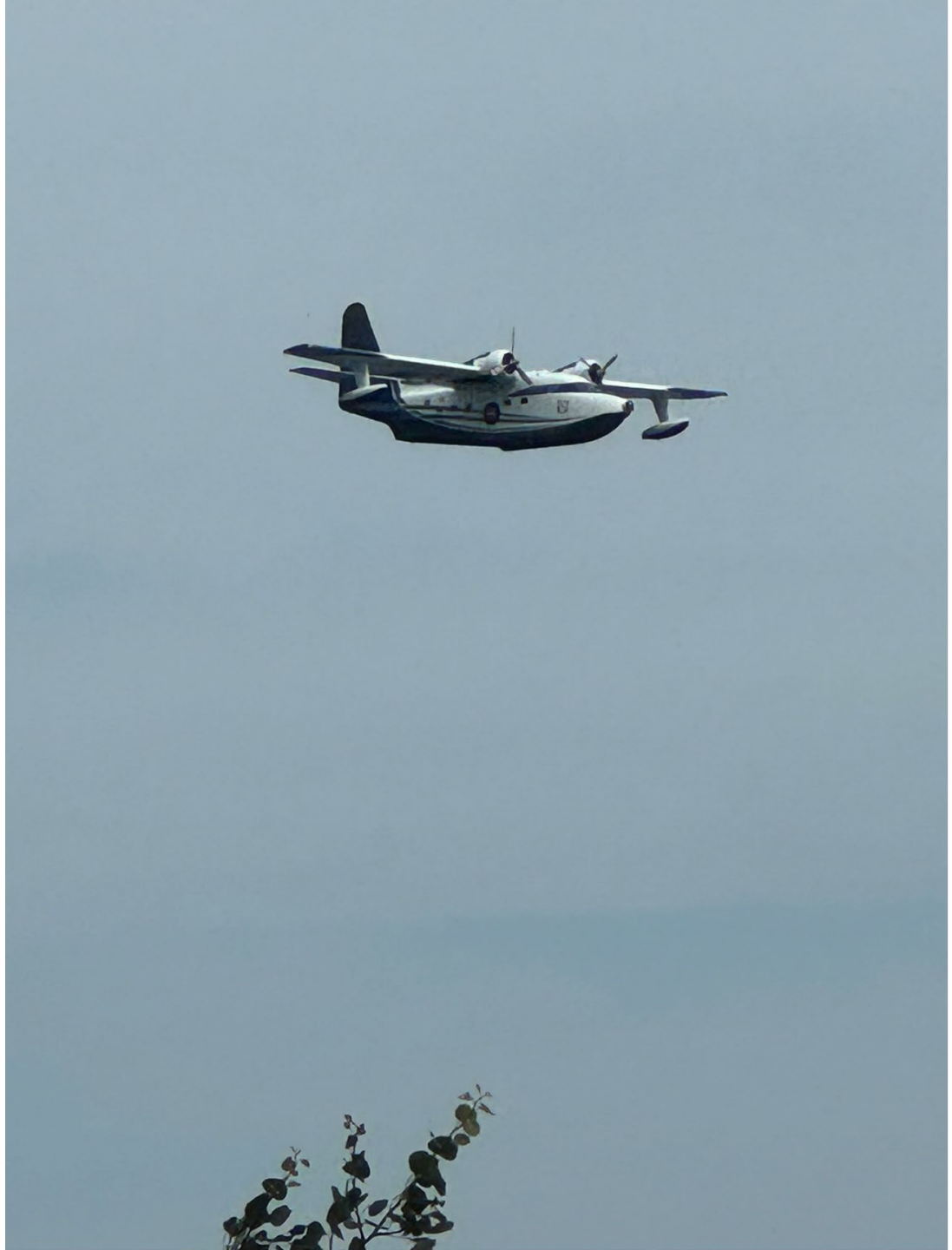
My understanding is that an organization cannot treat or bill Medicare patients differently than other payors. Is this supported by the False Claims Act? Why can't I find specific language saying it? Does hospital price transparency matter?

- It is impossible to treat everyone the same.
- "Discrimination" is illegal only when for an improper purpose.

Fredrikson

How far back must we go on a refund?

Fredrikson



Fredrikson

How far back must we go on a refund?

- Payor specific.
- Medicare: 48 months absent fraud or similar fault.
- Medicaid: Totally state dependent. Varies from forever to a few years.
- Private payors: Look at your contract. One-year lookbacks are common.

Fredrikson

Can Medicare advantage plans ignore Medicare rules?

- It depends. 42 CFR § 422.101 requires MA plans to “provide coverage of, by furnishing, arranging for, or making payment for, all services that are covered by Part A and Part B of Medicare.”
- Medicare advantage plans can be more generous than Medicare.

Fredrikson

As a physician, can I accept Medicare assignment at one of my businesses but not another?

- Opt-out is at the physician-level and not entity specific, so your opt-out status follows you.
- If you're participating in Medicare, any covered services you provide to Medicare beneficiaries must be submitted to Medicare.

Fredrikson

When can we provide medical information without a release?

- It depends.
- Under Federal law, HIPAA authorization is generally required unless the disclosure is for payment, treatment or health care operations (PTO).
- State law may require consent for certain PTO disclosures.
- Part 2-protected information? Be careful.

Fredrikson

What about that Reproductive Health Rule?

- On June 18, 2025, the U.S. District Court for the Northern District of Texas issued an order **vacating** the HIPAA Privacy Rule to Support Reproductive Health Care Privacy, published on April 26, 2024.
  - The Court's action was under its authority of vacatur vs. injunctive relief.
- Left intact are the amendments that require updates to Notice of Privacy Practice (NPP) provisions pertaining to substance use disorder regulations (42 CFR Part 2).
- Attestations are no longer required.
- Revise policies, training, etc.
- What's next?

Fredrikson

Can I use an AI scribe? Do I need patient consent?

- Health Privacy:
  - Review relationship with AI Scribe company to confirm compliance with HIPAA.
  - Confirm disclosure is protected under Business Associate Agreement.
  - Be wary of alternative compliance efforts.
  - Confirm state law.
- Consent for AI Use:
  - State law specific.
  - Best practice.

Fredrikson

What are our obligations regarding Interpreter Services?

- Reasonable steps to provide “meaningful access” to an individual with limited English proficiency (LEP).
- Language assistance services must be provided free of charge and in an accurate and timely manner.
- Restrictions on the use of certain persons to interpret or facilitate communication.
  - Adults not qualified as interpreters.
  - Minor children.
- Notice of nondiscrimination.

Fredrikson

What information can ICE require us to provide?

- Distinguish “require” from “request.”
- HIPAA permits sharing information with law enforcement, but state law often does not.
- ICE can access public space, but absent a warrant is not entitled to enter private areas.

Fredrikson

Can we provide free or discounted transportation to our facilities?

- Implicates the Anti-Kickback Statute and beneficiary inducement prohibitions in the Civil Monetary Penalties law.
- AKS safe harbor for free or discounted transportation.
    - Marketing and mileage restrictions, purpose requirements, “luxury” travel, and established patients.
- CMP pulls in AKS safe harbor.
- CMP safe harbor for promoting access to care.

Fredrikson

Can we provide free transportation from one of our facilities to another?

- It is often helpful to reframe a question. If a hospital offers a services in Manhattan, would anyone claim it is a kickback to open a new location providing the service in Brooklyn?
- If we can put the service in Brooklyn, why can’t we instead choose to drive the patient from Brooklyn to the existing service in Manhattan?
- Would the patient rather have the service in Brooklyn or have to take a bus to Manhattan?

Fredrikson

What is remuneration?

- United States ex rel. Martin v. Hathaway F.4th 1,043 (6th Cir. 2023) includes the following quote:

"There is one other problem with the broader definition. It lacks a coherent end point. Consider the hospital that opens a new research center, purchases top of the line surgery equipment, or makes donations to charities in the hopes of attracting new doctors. Or consider the general practitioner who refuses to send patients for kidney dialysis treatment at a local health care facility until it obtains more state-of-the-art equipment. Are these all forms of remuneration? Unlikely at each turn."

Fredrikson

What about small trinkets and gifts?

- Implicates the Anti-Kickback Statute and beneficiary inducement prohibitions in the Civil Monetary Penalties law.
- Legislative intent and OIG guidance for CMP.
- AKS analysis.
  - What is the intent?
  - State-specific AKS.

Fredrikson

If an LCD lists 6 covered diagnosis, and the patient we treated had condition not listed, can we appeal a denial? Is there any regulation you are aware of that says yes or no?

- NCDs are binding, LCDs are not.
  - An LCD is a coverage determination issued by a contractor, not promulgated by the agency, and is not even binding on an administrative law judge. See 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II) (QICs).
  - 42 C.F.R. 405.1062(a) (ALJs).
  - "The district court correctly stated in its instructions to the jury that LCDs are 'eligibility guidelines' that are not binding and should not be considered "the exact criteria used for determining" terminal illness."
  - *United States v. Aseracare, Inc.*, et al., 938 F.3d 1278, 1288 (11th Circ. 2019).

Fredrikson

Understanding How To Read an NCD/LCD

Where an item, service, etc. is stated to be covered, but such coverage is **explicitly limited to specified indications** or specified circumstances, all limitations on coverage of the items or services because they do not meet those specified indications or circumstances are based on §1862(a)(1) of the Act. **Where coverage of an item or service is provided for specified indications or circumstances but is not explicitly excluded for others, or where the item or service is not mentioned at all in the CMS Manual System the Medicare contractor is to make the coverage decision, in consultation with its medical staff, and with CMS when appropriate, based on the law, regulations, rulings and general program instructions.**

- Medicare National Coverage Determination Manual, CMS Pub. 100-03, Chapter 1, Foreword, Paragraph A

Fredrikson

Operationalizing NCDs

Indications and Limitations of Coverage
B. Nationally Covered Indications

Effective for services performed on or after February 15, 2018, CMS has determined that the evidence is sufficient to conclude that the use of ICDs, (also referred to as defibrillators) is reasonable and necessary:

1. Patients with a personal history of sustained Ventricular Tachyarrhythmia (VT) or cardiac arrest due to Ventricular Fibrillation (VF). Patients must have demonstrated:
   - An episode of sustained VT, either spontaneous or induced by an Electrophysiology (EP) study, not associated with an acute Myocardial Infarction (MI) and not due to a transient or reversible cause; or
   - An episode of cardiac arrest due to VF, not due to a transient or reversible cause.

2. Patients with a prior MI and a measured Left Ventricular Ejection Fraction (LVEF) ≤ 0.30. Patients must not have:
   - New York Heart Association (NYHA) classification IV heart failure; or,
   - Had a Coronary Artery Bypass Graft (CABG), or Percutaneous Coronary Intervention (PCI) with angioplasty and/or stenting, within the past

malfunction.

C. Nationally Non-Covered Indications

N/A

D. Other

For patients that are candidates for heart transplantation on the United Network for Organ Sharing (UNOS) transplant list awaiting a donor heart, coverage of ICDs, as with cardiac resynchronization therapy, as a bridge-to-transplant to prolong survival until a donor becomes available, is determined by the local Medicare Administrative Contractors (MACs).

All other indications for ICDs not currently covered in accordance with this decision may be covered under Category B Investigational Device Exemption (IDE)

Fredrikson

A Kyphoplasty LCD

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Provisions in this LCD and related coding article only address Vertebral Augmentation for Osteoporotic Vertebral Compression Fracture (VCF). Coverage will remain available for medically necessary procedures for other conditions not included in this LCD.

PVA (percutaneous vertebroplasty (PVP) or kyphoplasty (PKP)) is covered in patients with **BOTH** the following:

1. Inclusion criteria **(ALL are required)**:
    a. Acute (< 6 weeks) or subacute (6-12 weeks) osteoporotic VCF (T1 – L5), based on symptom onset, and documented by advanced imaging (bone marrow edema on MRI or bone-scan/SPECT/CT uptake) (1-3,10,25,27)

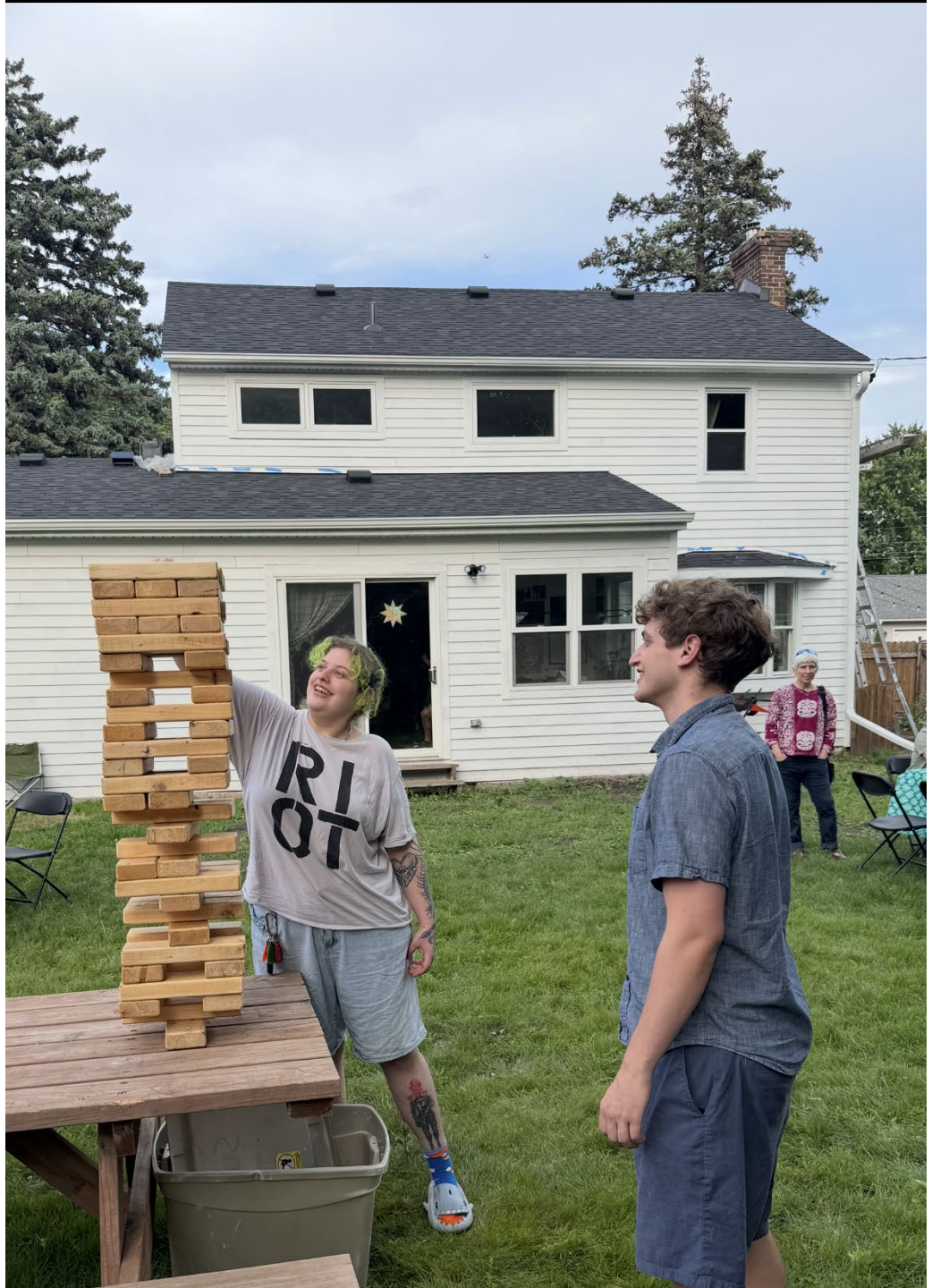
b. Symptomatic (**ONE**):
    i. Hospitalized with severe pain (Numeric Rating Scale (NRS) or Visual Analog Scale (VAS) pain score ≥ 8) (4-7)
    ii. Non-hospitalized with moderate to severe pain (NRS or VAS ≥5) despite optimal non-surgical management (NSM) (10) (**ONE**):
        1. Worsening pain
        2. Stable to improved pain (but NRS or VAS still ≥5) **(with ≥ 2 of the following):**
            A. Progression of vertebral body height loss
            B. > 25% vertebral body height reduction
            C. Kyphotic deformity
            D. Severe impact of VCF on daily functioning (Roland Morris Disability Questionnaire (RDQ) >17

c. Continuum of care (10) **(Both)**
    i. All patients presenting with VCF should be referred f

Fredrikson

What can you tell us about telehealth?

Fredrikson



Fredrikson

What can you tell us about telehealth?

- Absent Congressional action, Medicare coverage reverts 9/30.
- There is still a ton of poor thinking about where a service is provided.
- Logically, the patient's location, not the professional's, should control. (The government should discourage reimbursement arbitrage.)
- Keeping professional's home addresses out of claims is reasonable.
- In addition to reimbursement, licensure and malpractice insurance coverage issues remain. Fortunately, they haven't come up much.

Fredrikson

What's going on with prescribing controlled substances to a patient I've never seen in person?

- DEA and HHS extended flexibilities to allow prescribing through December 31, 2025.
- So, generally, you can do this.*
- January 17, 2025 – Issued proposed rules.
  - Comments closed March 18, 2025
- Watch for something by the end of year.

Fredrikson

What is the corporate practice of medicine?

- Governed by state law.
- Prohibits business entities from employing or controlling medical professionals or owning professional practices.
  - Seeks to prevent lay control over medical judgment.
  - Medicine, dentistry, veterinary, optometry, psychology.
- Friendly PC arrangement.

Fredrikson

Can anyone own a medspa?

- It depends.
- What services will the medspa provide?
- What about GLP-1s?
- Need to review your state's corporate practice of medicine doctrine.

Fredrikson

We’re doing a joint venture with a nonprofit . . .

- Does the nonprofit entity have to own 51%?
- A tax-exempt entity must have formal or informal control over the joint venture sufficient to ensure furtherance of charitable purposes.
  - Ownership.
  - Governance.
  - Put / call rights.

Fredrikson

Can I disclose PHI to a potential buyer in a deal?

- Yes, under HIPAA.
- But also check state law.
- Do I need a BAA?

Fredrikson

We’re doing a deal – what are some key notices or disclosures we should think about?

- Healthcare transactions laws (aka “mini HSR laws”).
  - Can vary by deal size, entity type, etc.
  - Notice v. consent.
- Facility licenses.
  - Structure might make a difference.
  - Note lead times!
- Medicaid / Medicare enrollment.

Fredrikson

Can I share the legal advice I get with others?

- Who are the “others?”
- Yes, but it risks waiving attorney-client privilege.
- Beware of the email forward.
- Share at your own risk.
- Copying the lawyer does not guarantee privilege.

Fredrikson

What do I do if I get a subpoenas for records?

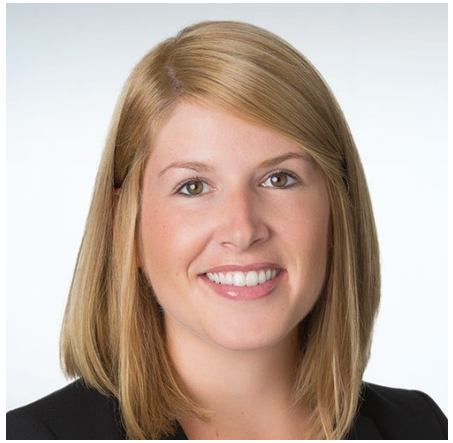
- Evaluate whether service is proper.
- Is there an authorization enclosed? Or on file?
- Determine whether HIPAA's requirements are met.
- Determine whether state law is more restrictive.
- Consider other reasons you may have to object.
- Consider discussing with the parties.

What's going on with pixels and other online tracking technologies?

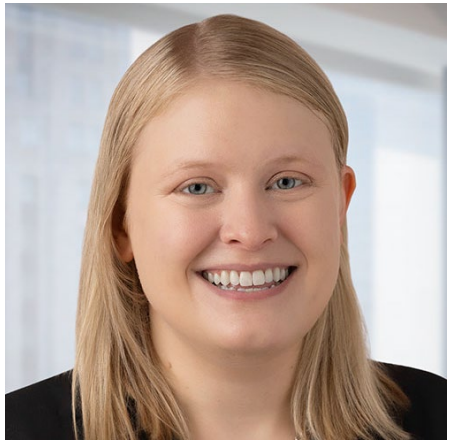
- What's the issue?
- HHS's Office of Civil Rights guidance partially vacated in June 2024.
- New lawsuit pace has slowed but still being filed.
- Current lawsuits progressing.
- Unclear what to expect from the government.
- Evaluate your exposure, goals, facts, and uses.
  - *See* November 2023 webinar.
- Check your insurance.

Fredrikson

Presenters

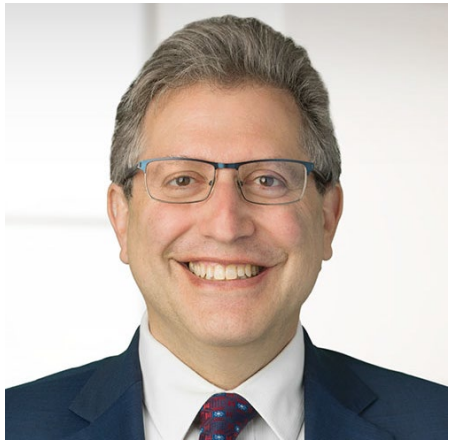


Margy Ahmann
Attorney
612.492.7495
mahmann@fredlaw.com



Amy Anderson
Attorney
612.492.7327
amyanderson@fredlaw.com

Katie Douglas
Attorney
612.492.7283
kdouglas@fredlaw.com



David Glaser
Attorney
612.492.7143
dglaser@fredlaw.com

Geoff Koslig
Attorney
612.492.7488
gkoslig@fredlaw.com

Fredrikson

Fredrikson

Where Law and Business Meet®