

Health Law FAQ 2026: Practical Answers to Common Questions

Health Law Webinar

August 12, 2026

Fredrikson

The logo for Fredrikson, featuring the name "Fredrikson" in a bold, black, sans-serif font. A red diagonal line is positioned below the "Fred" portion of the name.





Do We Have to Require Timesheets to Pay Our Medical Directors?

- “Must” vs. “Should”.
- Having them is helpful.
- Contractually requiring them is unhelpful.
- Avoid imposing a “requirement” on yourself that the law does not require.
- Understand differences between Stark and anti-kickback.

Is There Still A Prohibition On Entering Into The “Same or Similar” Contract for One Year After a Contract Terminates?

- Not exactly “one year after termination!” Stems from Stark, 42 CFR § 411.357.
- “If the lease arrangement is terminated with or without cause, the parties may not enter into a new lease arrangement for the same space[equipment] **during the first year of the original lease** arrangement.” 42 CFR § 411.357(a)(2), [(b)(3)]
- Personal service arrangements: If an agreement is terminated with or without cause, the parties may not enter into the same or substantially the same arrangement **during the first year of the original agreement.**” (d)(1)(iv)

What does “set in advance” mean for compensation? Can we say the hours will “as scheduled” based on patient care needs?

- (ii) Compensation is deemed to be “set in advance” if the aggregate compensation, a time-based or per-unit of service-based (whether per-use or per-service) amount, or a specific formula for calculating the compensation is set out in writing before the furnishing of the items, services, office space, or equipment for which the compensation is to be paid. The formula for determining the compensation must be set forth in sufficient detail so that it can be objectively verified.

Set In Advance: The Weeds.

- (ii) Notwithstanding [paragraph \(d\)\(1\)\(i\)](#) of this section, compensation (or a formula for determining the compensation) **may be modified at any time** during the course of a compensation arrangement and satisfy the requirement that it is “set in advance” if **all of the following conditions are met**:
 - (A) All requirements of an applicable exception in [§§ 411.355](#) through [411.357](#) are met on the effective date of the modified compensation (or the formula for determining the modified compensation).
 - (B) The modified compensation (or the formula for determining the modified compensation) is determined **before the furnishing** of the items, services, office space, or equipment for which the modified compensation is to be paid.
 - (C) Before the furnishing of the items, services, office space, or equipment for which the modified compensation is to be paid, the formula for the modified compensation is **set forth in writing in sufficient detail so that it can be objectively verified**.

42 CFR § 411.354(d)

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?
- Always ask “what would you rather explain to a jury?” As a general rule, anything that gives off “obfuscation” vives is unhelpful.



Any Updates On Gender Affirming Care?

- January 2025 Executive Order.
- December 2025 Proposed Rule regarding Conditions of Participation for Hospitals.
 - Received more than 30,000 comments received.
 - Comment period closed February 17, 2026.
 - No further action from HHS at this time, but public posts suggest intention to issue a final rule.
- Gender affirming care for minors is legally restricted in 27 states.

What is the Corporate Practice of Medicine?

- Governed by a patchwork of state law.
- Intent: Protect patient-physician relationship.
- 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.

A nonprofit in our rural area wants to establish a clinic for the poor. We have empty space and a doctor willing to volunteer. Can we give them space and a physician?

- Always consider Stark first.
- The nonprofit lacks owners, so Stark is likely inapplicable.
- Anti-kickback analysis: Does this sound like payments for referrals?
- Always ask whether someone will be making money off of a proposal.

We are a small rural hospital. When a critical patient arrives, it is almost impossible to treat other patients. Are we allowed to tell other patients there is going to be A wait? Does that violate EMTALA? If they ask us where the next closest hospital is, can we tell them?

- EMTALA requires a screening, and stabilization within the hospital's capabilities.
- “The hospital must provide for an appropriate medical screening examination within the capability of the hospital's emergency department, including ancillary services routinely available to the emergency department, to determine whether or not an emergency medical condition...exists. 42 USC §1395dd(a)
- In an emergency, the hospital must either “within the staff and facilities available at the hospital, for such further medical examination and treatment as may be required to stabilize the patient or “transfer the individual to another medical facility.” (Note the need for informed consent or physician certification that the benefit of transfer outweighs the risk.) 42 USC §1395dd(b)(c)

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.

Who is Considered “Clinical Staff” For Purposes of the TCM-required Outreach Call to a Patient?

- Clinical staff must contact the patient or their caregiver within 2 business days after the patient’s discharge from the inpatient or partial hospitalization setting.
 - Must be performed by clinical staff who can address patient status needs beyond scheduling follow-up care.
- “Clinical Staff” includes persons supervised by a physician or other qualified health care professional allowed by law, regulation, and facility policy to perform a specialized professional service.
- Certified Nurse Midwives, Clinical Nurse Specialists, Nurse Practitioners, and Physician Assistants may provide non-face-to-face TCM services “incident to” services of a physician.

Do We Have to Charge Every Patient the Same Amount?

- What is your charge? The answer isn't as easy as you might think.
- There is a very strong argument you don't charge everyone the same.
- The notation that disparate treatment is always “discrimination” is fundamentally incorrect. (To be fair, it is discrimination, but most discrimination is legal.)

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!

For Incident-to Billing Can The Physician Be “On-site” Virtually?

- No, but yes? At least for Medicare!
- Starting during the PHE supervision via audio/visual capability was allowed.
- Some consultants seem oblivious to this. The “office suite” test is now effectively irrelevant because the PHE started 6 years ago, past most statutes of limitation (but note the weird 10 year FCA in certain situations.)

Do We Always Bill Under The Supervising Physician?

- For services billed incident-to, the supervising physician “must” be the billing physician for Medicare. (But remember reassignment!)
- 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>.*

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)

What is the difference between “Price Transparency” and the “No Surprises Act?”

- The names imply more similarity than there is. “Price Transparency” only applies to hospitals and insurers, and requires publishing of every reimbursement rate for every code. (Ramifications still evolving.)
- The No Surprises Act has layers.
 - One applies to air ambulances, hospitals, ambulatory surgical centers, or freestanding emergency rooms. The rule unhelpfully defines them as “facilities.”
 - The second part of the rule requires a “Good Faith Estimates” of charges. While it also applies to “Facilities” the term is defined differently for this provision.

Have They Lost Their “Facilities?”

- For GFE purposes, a “Facility” is: Health care facility (facility) means an institution (such as a hospital or hospital outpatient department, critical access hospital, ambulatory surgical center, rural health center, federally qualified health center, laboratory, or imaging center) in any State in which State or applicable local law provides for the licensing of such an institution, that is licensed as such an institution pursuant to such law or is approved by the agency of such State or locality responsible for licensing such institution as meeting the standards established for such licensing.

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.

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.

Can We Offer Concierge Care? Can We Opt Out?

- Concierge care is nearly useless term. You can't charge a Medicare patient for covered services. That can make “concierge” programs for Medicare patients impractical.
- 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. A “cash only” telehealth service may run afoul of that. Should it?

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.

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.



Can I Use AI For Legal Research?

- Of course. But will it be right?
- The risk of AI taking your job may currently be lower than the risk of AI costing you your job!
- We use AI, but we check it a lot.

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.

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.
- Transport home is less risky.

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 Chicago, would anyone claim it is a kickback to open a new location providing the service in Des Plaines because parking is cheaper?
- If we can put the service in Des Plaines, why can't we instead choose to drive the patient from there to the existing service in Chicago?
- Would the patient rather have the service in Des Plaines or have to take a bus to Chicago?

What is Remuneration? If We Put in Fancy New Equipment in the OR, Is it a Kickback?

- 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.”

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.

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).

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

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

manipulation.

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)

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)

Created on 07/16/2025. Page 3 of 11

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

What Can You Tell Us About Section 6225 of the Consolidated Appropriations Act?

- CMS has proposed a regulatory framework to implement changes made by Section 6225 – including new requirements for hospital compliance related to off-campus outpatient departments.
- Hospitals must obtain a unique NPI for each off-campus outpatient department.
 - What does that mean?
- Standardized attestations for all departments.
- Public comments accepted through August 31.

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, 2026.
- Preventing disruption of care for patients relying on telemedicine.
- Extension does not change existing requirements.
 - Prescriptions issued for legitimate medical purposes, by licensed practitioners, in compliance with state and federal law.
- Watch for more by the end of year.

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.

Can I Provide Telehealth Care For My Current Patients Visiting Other States?

- Licensing requirements and scope of practice determinations vary by state.
- Generally speaking, a practitioner must be licensed in the state where the patient is located.
- Patchwork of state laws, some of which include exceptions to licensing requirements for consultation or limited provision of care.



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.

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.

Presenters



Amy Anderson

Attorney

612.492.7327

amyanderson@fredlaw.com



David Glaser

Attorney

612.492.7143

dglaser@fredlaw.com

Fredrikson



Where Law and Business Meet®