

Whistleblower Risk Management

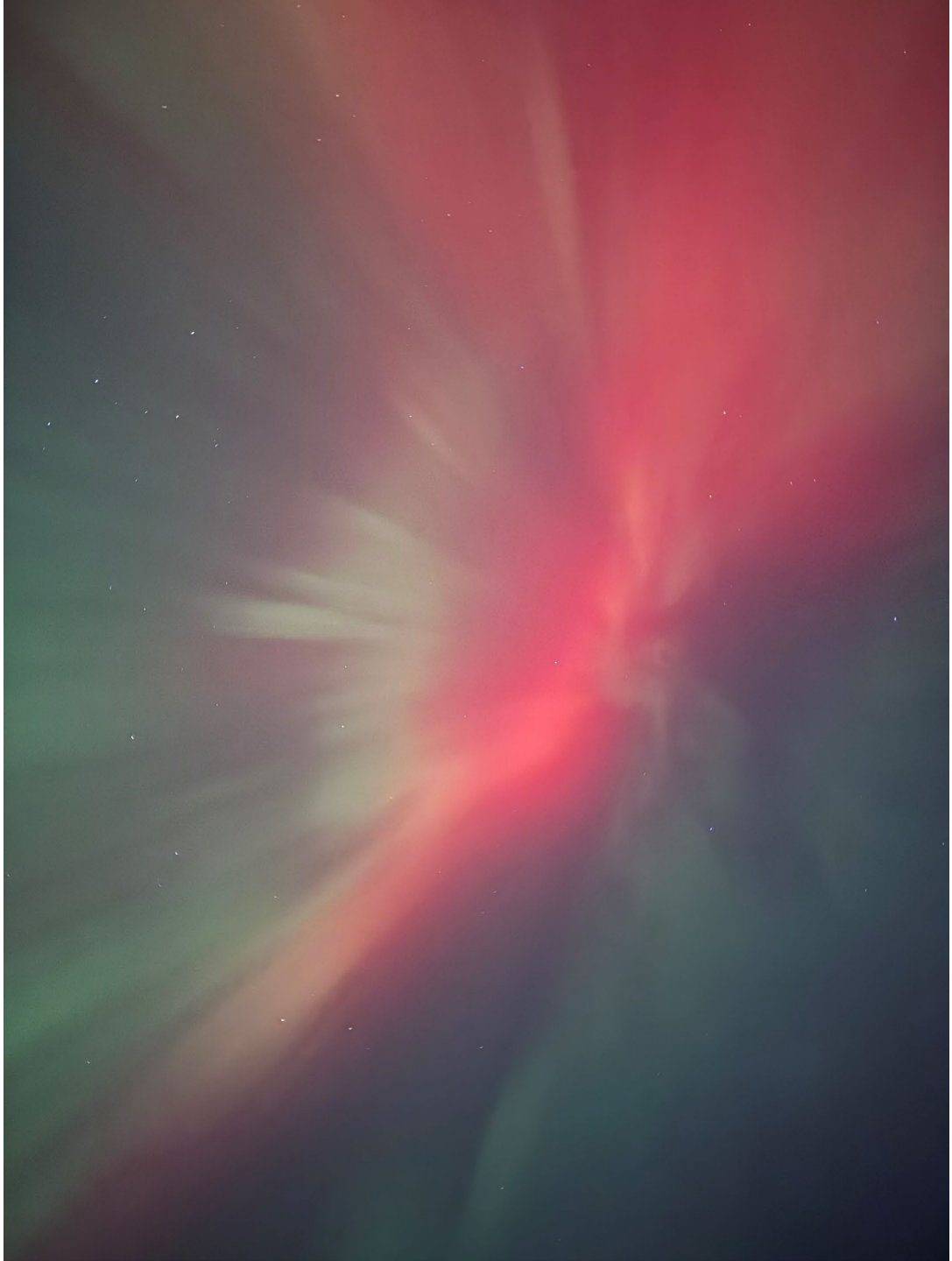
Health Law Webinar

November 12, 2025

Fredrikson

The logo for Fredrikson, featuring the name in a bold, black, sans-serif font. A red graphic element, consisting of a thick, upward-pointing chevron or wedge, is positioned beneath the 'F' and extends slightly to the right.





A Pop Tribute To Mike Reiling

- A contest in memory of a friend and colleague.
- He used to say that physician would justify their outlier status because they had sicker patients than everyone else.
- He referred to that as “terminal uniqueness.”
- Name the singer and song who has been afflicted with a terminal uniqueness.
- Hint: not all of my songs are from the 80s!!!



The Situation

- An employee contacts you with a range of concerns. An interventional cardiologist has nearly 30,000 RVUs. The employee believes the cardiologist is overcoding and is overcompensated.
- Patients have been complaining about long waits. Some appointments, scheduled for 5:00 p.m., actually occur at 7:00 or 7:30 at night. The cardiologist works with residents and compliance wonders if they are supervised.
- She has allowed her NP to treat new problems “incident to.”
- The cardiologist has been implanting ICDs in patients who don’t meet the criteria on the NCD.

The Situation

- To the extent there is an overpayment, how far back should we refund?
- The cardiologist's boyfriend is a sales rep for St. Jude's. Her daughter owns a catering company providing meals to the hospital.
- A device company pays the Dr. to give speeches.

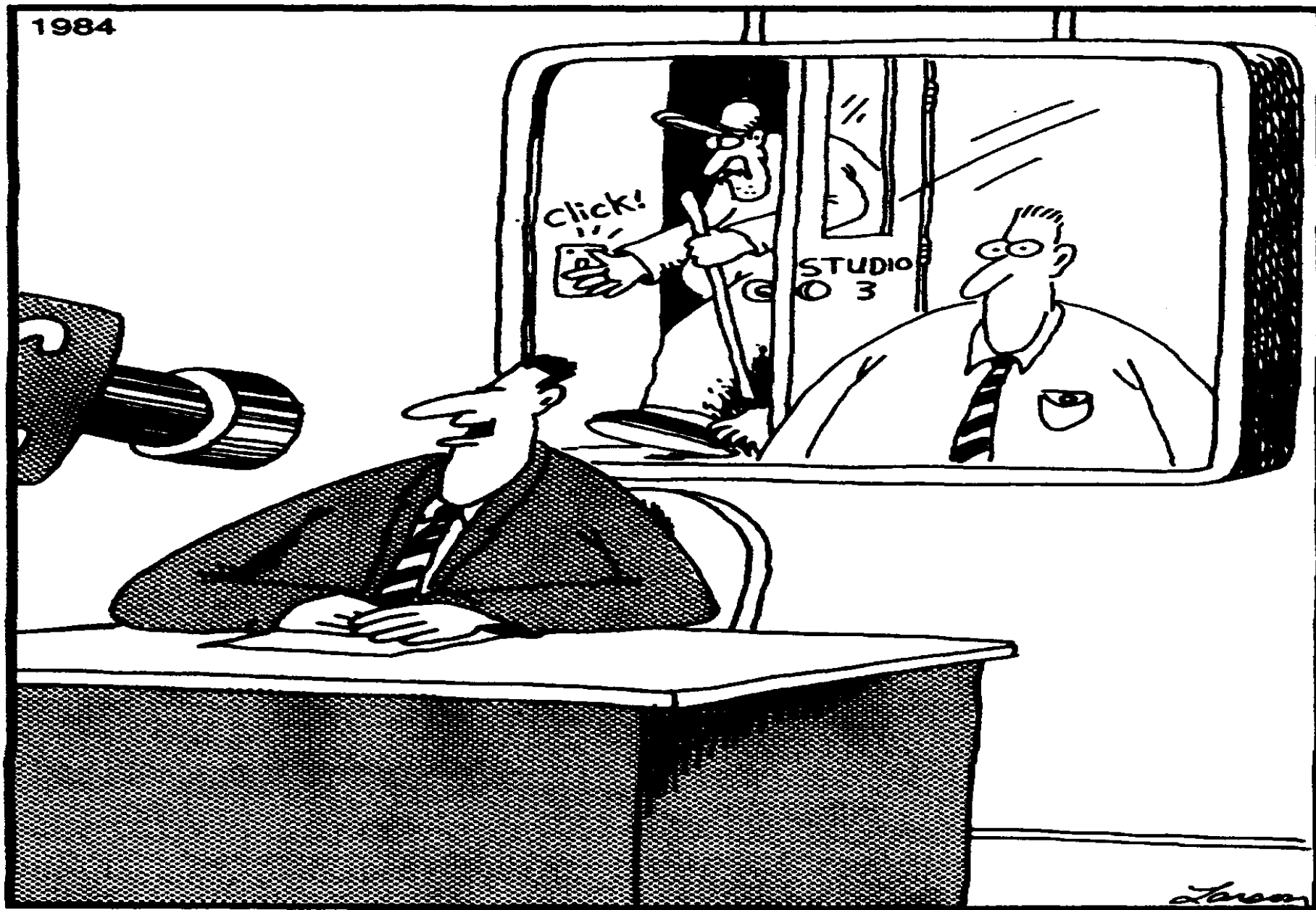
The Situation

- The employee is also concerned that we leased space to an independent cardiology practice. The lease was signed 20 years ago with rent far lower than other tenants in the building. There are discussions about us acquiring the practice.
- Allegations that we have been paying Dr. Bowie for call, but the payments vary from the contract, and Dr. Bowie hasn't been keeping time records.

What's Up, John?

- Make sure the employee understands your role.
- Ask lots of questions.
- The stopped clock axiom.
- Take things under advisement.
- Be careful with promises of confidentiality.

1984



“My next guest, on the monitor behind me, is an organized crime informant. To protect his identity, we’ve placed him in a darkened studio — so let’s go to him now.”

I Have Something to Cher: If I Could Turn Back Time

Employee Certifications: I Know Nothing!

- Consider asking all employees to attest that they are not aware of any compliance concerns.
- You will get lots of HR complaints.
- It prevents people from revisionist reporting.

A Total Release: Separation Agreement Tips

- Employees can't promise not to bring a qui tam.
- We don't want to look like we're inhibiting government reports.
- **An employee can promise not to keep the relator's share of a qui tam.**

A Big Question

- Do you care about privilege?

A Big Question

- Do you care about privilege?
- The easy answer is yes, but what about the 60 day rule?
- For kickback, quality, medical necessity and med. mal. issues privilege may matter.
- For refunds, it really may not!

Privilege: Must The Lawyer Do The Outreach?

Attorney-Client Privilege

- Communications from the client as well as advice from the attorney and **retained agents**.
- Oral and written communications.
- Key issue: whether the communication was in furtherance of obtaining legal advice? The lawyer must be in charge.

Work Product Privilege

- Materials prepared or assembled at the direction of counsel.
- Must be in anticipation of potential litigation.
- Overcome if there is “substantial hardship.”
- Opinion/mental impressions receive higher protection.
- Note that you can have AC but NOT work product for consultant work if not anticipating litigation.

Quick Note About Peer Review

- In many states this is a “protection,” not a privilege.
- Surprisingly, “protections” can be stronger!!
- (With surveyors, exercising this privilege comes with peril. See Illinois Council. Perhaps a recent 340B case a crack in Illinois Council?)

What Is Privileged?

- Facts are NOT protected, just analysis.
- Exceptions to privilege:
 - Presence of unauthorized third party.
 - Overbroad dissemination of privileged information.
 - Waiver.
 - Business versus legal advice.
 - Crime/fraud exception.

Protecting Privilege

- Make sure everyone knows legal is involved.
- Upjohn warning.
- Request for confidentiality.
 - Co-workers.
 - Family.
 - Government?
- What if the employee wants to bring counsel?

Must You Label Communications?

- Not required, but it can simplify review.
- Accuracy matters.

Tiger Traps: Happy Hoppe

- You label a document as “work product.”
- That means you think there is a risk of litigation.
- Have you just created a duty of document preservation??

Hiring Consultants

- Attorney Client or Work Product?
- Discuss the consultant's role; is s/he an advocate or a cop?
- Get references. There are some horror stories.

Should I Record The Meeting?

Should I Record The Meeting?

- NO, NO, NO.
- Possible impact on the employee.
- May make the discussion discoverable.
- Even a signed statement is at higher risk of discovery.

Interview Tips





2081239

Interview Tips

- Make people comfortable. Consider geography.
- Let them talk! Choose your questions thoughtfully. Enjoy the silence.
- Educate your witness.
- No need to be conventional.
- Do you tell people they are/aren't a target?
- Phone interviews can be great when documents aren't important.

The Opening Spiel

- Pleasantries.
- Upjohn.
- Do you know why we are here? (If appropriate, include reassurance, but only if appropriate!)
- Do you watch TV cop shows?
- Can't tell you what others say.
- Document preservation/Fawn Hall.
- Their work/education history.

Something To Ponder



**"Now calm down there, ma'am. ... Your cat's gonna be fine
... just fine."**

Other Considerations

- Defamation/Embarrassment.
- Damaging relationships.
- Creating whistleblowers.
 - What do you say to outside parties? Who do you call there?
 - What do you say to other employees?
- Obstruction of Justice/harming credibility.





Change in the 60 Day Rule

- It used to be you could take about 6 months to determine if you have an overpayment.
- Now you get 180 days.
- Refund is due at the earlier of 180 days or your determination you owe the money.

If You Do Refund, to Whom?

- Provider Self-Disclosure Protocol.
- Self-Referral Disclosure Protocol.
- US Attorney's Office.
- Medicare Administrative Contractor.
- Medicaid agency.

Poll: How Far Back Must You Go?

- Forever.
- 10 Years.
- 6 years.
- 5 years after the year in which payment was made.
- 4 years.
- 3 years.
- 1 year.

How Far Back Must You Go?

- Two statutory provisions limit recovery of overpayments, 1870 and 1879. 1870 seems like a statute of limitation. Note neither statutes mentions “reopening.”
- 1870 focuses on “without fault” and includes a time frame, 1879 uses “did not and should not” have known, no timeframe.
- Regulations limit “reopening,” are silent on recovery.
- Manuals both limit reopening and recovery.







Social Security Act §1870

- (c) There shall be no adjustment as provided in subsection (b) (nor shall there be recovery) in any case where the incorrect payment has been made (including payments under section 1814(e)) **with respect to** an individual who is **without fault** **or** where the adjustment (or recovery) would be made by decreasing payments to which another person who is without fault is entitled as provided in subsection (b)(4), **if such adjustment** (or recovery) would defeat the purposes of title II or title XVIII **or would be against equity and good conscience.**

Social Security Act §1870

Adjustment or recovery of an incorrect payment (or only such part of an incorrect payment as the Secretary determines to be inconsistent with the purposes of this title) against an individual who is without fault shall be deemed to be against equity and good conscience **if** (A) the incorrect payment was made for expenses incurred for items or services for which payment may not be made under this title by reason of the provisions of paragraph (1) or (9) section 1862(a) **and**

(B) if the Secretary's determination that such payment was incorrect was made subsequent to the third [**FIFTH**] year following the year in which notice of such payment was sent to such individual; **except that the Secretary may reduce such three-**[FIVE]** year period to not less than one year if he finds such reduction is consistent with the objectives of this title.**

How Does §1870 Work?

- Focus only on the YEAR payment is made.
- Payment made 1/4/20. Can recover 5 years after 2020, so count: 2021, 22, 22, 24, 25. Recovery possible through 12/31/25.
- Payment made 12/31/19. So 2020, 21, 22, 23, 24. Recovery until 12/31/24.
- Note that references to “five years” are very misleading. In life, simplicity too often trumps accuracy.

Social Security Act §1879

- (a) Where -- (1) a determination is made that, **by reason of section 1862(a)(1) or (9)** or by reason of a coverage denial described in subsection (g), payment may not be made under part A or part B of this title for any expenses incurred for items or services furnished an individual by a provider of services or by another person pursuant to an assignment under section 1842(b)(3)(B)(ii), and (2) both such individual and such provider of services or such other person, as the case may be, **did not know, and could not reasonably have been expected to know**, that...

Social Security Act §1879

payment would not be made for such items or services under such part A or part B, then to the extent permitted by this title, payment shall, notwithstanding such determination, be made for such items or services (and for such period of time as the Secretary finds will carry out the objectives of this title), as though section 1862(a)(1) and section 1862(a)(9) did not apply and as though the coverage denial described in subsection (g) had not occurred...Any provider or other person furnishing items or services for which payment may not be made by...

Social Security Act §1879

reason of section 1862(a)(1) or (9) or by reason of a coverage denial described in subsection (g) shall be deemed to have knowledge that payment cannot be made for such items or services if the claim relating to such items or services involves a case, provider or other person furnishing services, procedure, or test, with respect to which such provider or other person has been notified by the Secretary (including notification by a quality improvement organization) that a pattern of inappropriate utilization has occurred in the past, and such provider or other person has been allowed a reasonable time to correct such inappropriate utilization.

The Government Wants Refunders To Ignore §1879

- “We believe it is inappropriate for providers or suppliers to make determinations regarding their own knowledge of non-coverage or whether they were the cause of an overpayment in lieu of reporting and returning an identified overpayment as required by this rule.”

– 81 FR 7666

42 C.F.R. §405.980

(b) A contractor may reopen an initial determination or redetermination on its own motion—

(1) Within 1 year from the date of the initial determination or redetermination for any reason.

(2) Within 4 years from the date of the initial determination or redetermination for good cause as defined in §405.986.

(3) At any time if there exists reliable evidence as defined in §405.902 that the initial determination was procured by fraud or similar fault as defined in §405.902.

42 C.F.R. §405.902

- “Similar fault” means “to obtain, retain, convert, seek, or receive Medicare funds to which a person knows or should reasonably be expected to know that he or she or another for whose benefit Medicare funds are obtained, retained, converted, sought, or received is not legally entitled. This includes, but is not limited to, a failure to demonstrate that he or she filed a proper claim...”
- 42 CFR § 411.21 defines a “proper claim” as a “claim that is filed timely and meets all other claim filing requirements specified by the plan, program, or Insurer.”

How Far Back Must You Go?

- “An overpayment must be reported and returned in accordance with this section if a person identified the overpayment, as defined in paragraph (a)(2) of this section, within 6 years of the date the overpayment was received.”

– 42 CFR 401.305(f)

CMS Thinks You Must Do More Than Contractors

- “Comment: Commenters questioned whether they had a responsibility to go back beyond the 3 years covered in a Recovery Audit Contractor (RAC) audit that identifies overpayments.
- Response: Yes, as discussed previously, this final rule clarifies that when the provider or supplier receives credible information of a potential overpayment, they need to conduct reasonable diligence to determine whether they have received an overpayment.

CMS Thinks You Must Do More Than Contractors

- RAC audit findings, as well as other Medicare contractor and OIG audit findings, are credible information of at least a potential overpayment. Providers and suppliers need to review the audit findings and determine whether they have received an overpayment. As part of this review, providers and suppliers need to determine whether they have received overpayments going back 6 years as stated in this rule.”

– 81 FR 7672

Bottom Line

- The government thinks you must go back six years (Even if the contractor doesn't go back as far!)
- We think they lack the statutory authority for this. If the government can't reopen the claim, IT ISN'T AN OVERPAYMENT!!!
- You must choose the route you are comfortable with.



Conceptualizing The Law

- Note the Medicare legal hierarchy:
 - Constitution, statute, regulation, NCD.
 - LCD, preamble, manual, carrier guidance.
- Proposed Rule vs. Final Rule.
- Not all laws are criminal.
- Some are counter-intuitive/contradictory.
- Never forget state law. Some are mighty hard to find!! (Is local counsel an advantage???)

How Does One Validate 30,000 RVUs?

How Does One Validate 30,000 RVUs?

- Documentation review.
- Interview co-workers.
 - NPPs and staff?
 - Fellow physicians? (beware of jealousy)
 - Current residents?
 - Former residents?
- Shadowing?
- Patient complaints.

How Do You Assess FMV For Comp?

Death Of Common Sense (And Math)?

- Survey says?
 - Is 50th percentile a ceiling? What about 75th? 90th?
- Conventional wisdom in this area is awful. True analysis seems rare.
- FMV is supposed to ignore presence of referrals. Is that even possible?

Surveying The Environment

- Meghan Wong at MGMA has explained "the data are not intended to be used as an academic data set for extrapolating to the U.S. population of physicians," and are not a "one-to-one representation of the universe of medical practices that are in the country."*
- High and low responses are thrown out.

*Thanks to Tim Smith, TS Healthcare Consulting

Surveying The Environment

- Do people understand “total compensation?”
- Is there an inverse relationship between productivity and per RVU compensation?
- Do groups comply with the “professional data only, no technical fees” request?



Analyze This

- 90th Percentile Interv. Card. CF in 2012:
 - AMGA: \$102.06 MGMA: \$86.47
- 90th Percentile RVU IC.:
 - 2009 16,758
 - 2010 18,316
 - 2011 16,136
 - 2012 15,208 (20% swing from 2010!)

“We Lose Money On Every Physician.”

- If true, is this a problem?
- Is it true?
 - How is overhead calculated and allocated?
 - How is revenue allocated?
- What about ancillaries?

Allegation: New Problems Were Billed As “Incident to” to Medicare

Can You Treat “New Problems” “Incident To”?

- Essentially every MAC says no.

What It Isn't

- Incident to is not
 - A visit by an established patient for new problem
 - Services which have their own coverage requirements and benefit category
 - Services provided by residents, medical students
 - Services of scribes
 - IPPE, also known as “Welcome to Medicare Preventive Visit”
 - Goals of IPPE are health promotion and disease prevention and detection

42 C.F.R. §410.26(b)

Medicare Part B pays for services and supplies incident to the service of a physician (or other practitioner).

(1) Services and supplies **must be furnished in a noninstitutional setting to noninstitutional patients.**

(2) Services and supplies must be an **integral, though incidental**, part of the service of a physician (or other practitioner) in the **course of diagnosis or treatment** of an injury or illness.

MBPM Chapter 15§60.1.B

Thus, where a physician supervises auxiliary personnel to assist him/her in rendering services to patients and includes the charges for their services in his/her own bills, the services of such personnel are considered incident to the physician's service if there is a physician's service rendered to which the services of such personnel are an incidental part and there is direct supervision by the physician.

“Course Of Treatment*” MBPM Chapter 15§60.1.B

This does not mean, however, that to be considered incident to, **each occasion of service by auxiliary personnel** (or the furnishing of a supply) **need also always be the occasion of the actual rendition of a personal professional service by the physician**. Such a service or supply could be **considered to be incident to when furnished during a course of treatment where the physician performs an initial service and subsequent services of a frequency which reflect his/her active participation in and management of the course of treatment***.

*What happened to diagnosis???

What Is A “Course Of [Diagnosis Or] Treatment”?

- Patient receiving chemo develops an infection.
- Child has a series of ear infections. What if they now get strep throat?
- Is the course of diagnosis broader?
- NEITHER THE REGS NOR THE MANUAL MENTION “NEW PROBLEM.”

The “New Problem” Problem

- Do you “diagnose” old problems??



The Checklist

- If someone makes an assertion (you can't do incident to for a patient with a new problem):
 - Make them show you the rule.
 - Read what they give you carefully. Does it say what they think it says?
 - Consider the hierarchy. Is what they provided truly binding?

The Florida Project

- Client says they have heard from the MAC the physician must perform a “substantive” portion of the visit, defined as one of the CPT’s “key components,” i.e., history, exam or medical decision-making.
- Manual said “physician provides any face-to-face portion of the E/M encounter with the patient.”
- Are those the same? “How are you?” Is MDM face-to-face?

First Coast Website

Split and shared visits FAQ

Q: What is a split/shared visit? Can you provide an example?

A: A split/shared evaluation and management (E/M) visit is defined by Medicare Part B payment policy as a medically necessary encounter with a patient where the physician and a qualified non-physician practitioner (NPP) each personally perform a substantive portion of an E/M visit face-to-face with the same patient on the same date of service.

• A substantive portion of an E/M visit involves all or some portion of the history, exam or medical decision making key components of an E/M service.

• The physician and NPP both must be in the same group practice or employed by the same employer.

The split/shared E/M visit applies only to selected E/M visits and settings (i.e., hospital inpatient, hospital outpatient, hospital observation, emergency department, hospital discharge, office and non-facility clinic visits, and prolonged visits associated with these E/M visit codes). The split/shared E/M policy does not apply to critical care services or procedures.

Common split/shared visit scenarios

• Hospital inpatient/outpatient/emergency room setting:

• When a hospital inpatient/hospital outpatient or emergency department E/M is shared between a physician and an NPP from the same group practice and the physician provides any face-to-face portion of the E/M encounter with the patient, the service may be billed under either the physician's or the NPP's National Provider Identifier(NPI).

• If there was no face-to-face encounter between the patient and the physician (e.g., even if the physician participated in the service by only reviewing the patient's medical record) then the service may only be billed under the NPP's NPI.

• Payment will be made at the appropriate physician fee schedule rate based on the Provider Transaction Access Number (PTAN) entered on the claim.

EXAMPLE: If the NPP sees a hospital inpatient in the morning and the physician follows with a later face-to-face visit with the patient on the same day, the physician or the NPP may report the service.

EXAMPLE: In an office setting the NPP performs a portion of an E/M encounter and the physician completes the E/M service. If the "incident to" requirements are met, the physician reports the service. If the "incident to" requirements are not met, the service must be reported using the NPP's NPI.

Documentation for split/shared visits should follow the documentation guidelines for any E/M service: each physician/NPP should personally document in the medical record his/her portion of the E/M split/shared visit and legibly sign and date the record. The documentation must support the combined service level reported on the claim

Allegation: Teaching Physicians Were Not Present

Teaching Physician Services

- Medicare pays hospitals to train residents.
- Therefore, it would be “double-dipping” to count the resident’s work.
- Act as if the resident didn’t exist.
- Lessons from Baylor:
 - Beware the overbroad certification!
 - Fight the madness! The government claimed the physician must complete one case before starting the next. (There is some manual language that can be read that way. It is obviously wrong.)
 - The government included the hospital payment in damages.

Medicare Claims Processing Manual

§100.1.2 – Surgical Procedures

Two Overlapping Surgeries

In order to bill Medicare for two overlapping surgeries, the teaching surgeon must be present during the critical or key portions of both operations. Therefore, the critical or key portions may not take place at the same time. **When all of the key portions of the initial procedure have been completed, the teaching surgeon may begin to become involved in a second procedure.** The teaching surgeon must personally document in the medical record that he/she was physically present during the —

Medicare Claims Processing Manual

§100.1.2 – Surgical Procedures

critical or key portion(s) of both procedures. When a teaching physician is not present during non-critical or non-key portions of the procedure and is participating in another surgical procedure, he/she must arrange for another qualified surgeon to immediately assist the resident in the other case should the need arise. **In the case of three concurrent surgical procedures, the role of the teaching surgeon (but not anesthesiologist) in each of the cases is classified as a supervisory service to the hospital rather than a physician service to an individual patient and is not payable under the physician fee schedule.**

Medicare Claims Processing Manual

§100.1.2 – Surgical Procedures

A. Surgery (Including Endoscopic Operations)

The teaching surgeon is responsible for the preoperative, operative, and postoperative care of the beneficiary. **The teaching physician's presence is not required during the opening and closing of the surgical field unless these activities are considered to be critical or key portions of the procedure.** The teaching surgeon determines which postoperative visits are considered key or critical and require his or her presence.

42 C.F.R. §415.172

(a) General rule. If a resident participates in a service furnished in a teaching setting, physician fee schedule payment is made only if a teaching physician is present during the key portion of any service or procedure for which payment is sought. In residency training sites that are located outside a metropolitan statistical area, physician fee schedule payment may also be made if a teaching physician is present during the key portion of the service, including for Medicare telehealth services, through audio/video real-time communications technology for any service or procedure for which payment is sought. For all teaching settings during the Public Health Emergency, as defined in §400.200 of this chapter, for the COVID-19 pandemic, if a resident participates in a service furnished in a teaching setting, physician fee schedule payment is made if a teaching physician is present during the key portion of the service including for Medicare telehealth services, through audio/video real-time communications technology for any service or procedure for which payment is sought.

42 C.F.R. §415.172

(1) In the case of **surgical**, high-risk, or other complex procedures, the teaching physician must be **present during all critical portions** of the procedure and **immediately available** to furnish services **during the entire service** or procedure.

42 C.F.R. §415.172

- (i) In the case of surgery, the teaching physician's presence is **not required during opening and closing of the surgical field.**
- (ii) In the case of procedures performed through an endoscope, the teaching physician must be present during the entire viewing.

42 C.F.R. §415.172

(2) In the case of **evaluation and management** services, except as otherwise provided in this paragraph (a)(2), the teaching physician must be **present in person during the portion of the service that determines the level of service billed**. (However, in the case of evaluation and management services furnished in hospital outpatient departments and certain other ambulatory settings, the requirements of §415.174 apply.)

42 C.F.R. §415.172

- (i) In residency training sites that are located **outside of a metropolitan statistical area, the teaching physician may be present through audio/video real-time communications technology** during the portion of the service that determines the level of service billed. (However, in the case of evaluation and management services furnished in hospital outpatient departments and certain other ambulatory settings, the requirements of §415.174 apply.)
- (ii) For all teaching settings during the Public Health Emergency, as defined in §400.200 of this chapter, for the COVID-19 pandemic, the teaching physician may be present through audio/video real-time communications technology during the portion of the service that determines the level of service billed. (However, in the case of evaluation and management services furnished in hospital outpatient departments and certain other ambulatory settings, the requirements of §415.174 apply.)

An Explicit Documentation Requirement

- (b) Documentation. Except as otherwise provided in this paragraph (b), except for services furnished as set forth in §415.174 (concerning an exception for services furnished in hospital outpatient and certain other ambulatory settings), §415.176 (concerning renal dialysis services), and §415.184 (concerning psychiatric services), the medical records must document that the teaching physician was present at the time the service (including a Medicare telehealth service) is furnished. The presence of the teaching physician during procedures and evaluation and management services may be demonstrated by the notes in the medical records made by the physician or as provided in §410.20(e) of this chapter.

Who Can Write In The Medical Record?

- Historically, anyone.
- Be careful what you wish for—

42 CFR § 410.20(e)

Medical record documentation: The physician may review and verify (sign/date), rather than re-document, notes in a patient's medical record made by physicians; residents; nurses; medical, physician assistant, and advanced practice registered nurse students; or other members of the medical team including, as applicable, notes documenting the physician's presence and participation in the services.

Allegation: The Physician Was Implanting ICDs When the NCD Prohibits Coverage

The ICD NCD: How 150 Hospitals Got It Wrong

National vs. Local Coverage Determinations

- NCDs are binding.
- They are also less restrictive than most people think.

NCDs Are Complicated

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	
indication.	
C. Nationally Non-Covered Indications	ents must have
N/A	yocardial
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).	hin the post
All other indications for ICDs not currently covered in accordance with this decision may be covered under Category B Investigational Device Exemption (IDE)	

LCDs

- Issued by contractor.
- Apply to limited contractor's geographic territory.
- Subject to notice-and-comment (Program Integrity Manual 13.2.4.2).

Role Of LCDs

- 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 Cir. 2019).

If You See Something, Say Something?

- Internal and external reporting duties are very different.
- If you see a bank robbery, must you call the police?
- Note the 60-day rule.
 - Return overpayments within 60 days of identification.
 - This only applies to OVERPAYMENTS.
- Beware of licensing board obligations.

Allegation: A Device Company Was Paying The Physician To Give Speeches

Medicare Antikickback Statute

- It is illegal to offer, solicit, make or receive any payment intended to influence referrals under a federal health care program.
- The government applies the “one purpose” test. If one purpose of the payment is to influence referrals, the payment is illegal.

Antikickback Statute

- Intent is everything. The question: Is the payment intended to curry favor? Keep asking “why?”
- If the payment is “bait” to get someone to listen, there is a defense. If the gift is to get someone to act, make sure you have extra reading material and someone to watch the dog.
- A “kickback” should require 3 parties, and arguably, deception.

Antikickback Protection

- Safe harbors exist, but they are VERY narrow.
- They will cover payments for services as long as the payment is reasonable for the work done.
- Common sense takes you a long way with the antikickback law. Remember, you don't need to fit in a safe harbor.
- Different lawyers can approach this VERY differently. Understand how yours does. ("We didn't find an advisory opinion, suggesting this is illegal...")

Which Is Better, A or B?

- A: Device company pays dozens of doctors \$20,000 each to promote their product. The total outlay is around \$1 million.
- B: Device company pays 4 doctors \$250,000 each to promote their product. The doctors give dozens of talks a year. The total outlay is \$1 million.

Perspective Check: Safe Harbors Aren't Key

“Arrangements are not necessarily unlawful because they do not fit in a safe harbor. Arrangements that do not fit in a safe harbor are analyzed for compliance with Federal anti-kickback statute based on the totality of their facts and circumstances, including the intent of the parties.”

–85 F.R. 77685.

Physician/Hospital Safe Harbor

- Investment terms cannot be related to referrals.
- Hospital cannot lend/provide guarantee to doctors to finance the venture.
- Payout proportional to investment.
- No discrimination against federal beneficiaries.
- No use of hospital space/equipment without safe harbor-compliant lease.

Physician/Hospital Safe Harbor

- All ancillaries to government points must be related to ASC services and services must be billed by ASC.
- Hospital cannot include costs on cost report.
- Hospital may not be in a position to make or influence referrals directly or indirectly to any investor.

Civil Monetary Penalties

- Permits fines for payments that are “likely to influence” a beneficiary to order or receive services from a particular provider, practitioner, or supplier.
- 42 U.S.C. 1320a-7a.

What Is Remuneration?

- Not everything of value is remuneration.
- A civil monetary penalty provisions carves out certain value from remuneration.
- SSA §1128A(i)(6)(F), 42 U.S.C. 1320a–7a(i)(6)(F), excludes from remuneration “any other remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs (as defined in section 1128B(f) and designated by the Secretary under regulations).”

(3) If an arrangement meets all of the requirements to be protected by an exception to the Beneficiary Inducements CMP, would that arrangement also automatically be protected under the Federal anti-kickback statute?

No. The exceptions to the definition of “remuneration” under the Beneficiary Inducements CMP at section 1128A(i)(6) of the Act and 42 CFR § 1003.110 do not provide protection from sanctions under the Federal anti-kickback statute. However, one of the exceptions to the definition of “remuneration” under the Beneficiary Inducements CMP applies to “any permissible practice described in any subparagraph of section 1128B(b)(3) or in regulations issued by the Secretary.” Therefore, any practice that is protected by an exception or safe harbor to the Federal anti-kickback statute also is excepted from the definition of “remuneration” under the Beneficiary Inducements CMP (i.e., such practice does not violate the Beneficiary Inducements CMP), but the reverse is not true.

General Questions Regarding Certain Fraud and Abuse Authorities |
Office of Inspector General | Government Oversight | U.S.
Department of Health and Human Services

Does That Analysis Make Sense?

- Congress created the CMP exceptions to “promote access to care.”
- Congress worried that fear of fines would cause people to refrain from promoting access to care.
- If someone says to you “we promise not to fine you, but we might put you in jail,” how safe do you feel?

Remuneration Under Anti-kickback

- Appears that intangibles are NOT remuneration.
- *U.S. ex rel Martin v. Hathaway*, 2023 WL 2661358 (6th Cir., March 28, 2023), “The statute does not define remuneration. At stake is whether it covers just payments and other transfers of value or any act that may be valuable to another. For the reasons that follow, it covers just payments and other transfers of value.”
- How does this impact:
 - Turn around times.
 - Asst. at surgery.
 - NPPs to round.

Allegation: The Physician's Daughter Owns a Catering Business Proving Food to the Hospital



Stark

- If a physician (or immediate family member) has a financial relationship with an organization that provides Designated Health services, “DHS” **ordered** by the physician, Stark applies. Any value will do it.
- Note the word “ordered.” While everyone refers to “referrals,” Stark defines “referral” as “creating a plan of care.”
- “Immediate family” includes husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild. **Beware of relatives!!!!**

Stark

- Financial relationships can be ownership or compensation.
- 3 exceptions protect both ownership and compensation. The others only protect one or the other.
- Stark is less likely to be a factor when the other party is another 501(c)(3). If the other party is owned by physicians, we DEFINITELY should consider Stark.

“Designated Health Services”

- Clinical laboratory.
- Physical therapy.
- Occupational therapy.
- Radiology services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrition.
- Prosthetics and orthotics.
- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpt. hospital services.
- Outpt. SLP services.

EKRA

- Eliminating Kickbacks in Recovery Act.
- Much like anti-kickback, BUT fewer exceptions.
- Biggest impact on us: Lab. Payments to employees that WERE kosher may not be now.

“It’s Not A Conflict Because I Disclosed It!”

- Not true, but....



Tax Exemption

- “Private inurement” occurs when a person gets an undeserved benefit from a tax exempt organization.
- “Intermediate sanctions” allow the IRS to recoup the money, plus penalties, from the recipient.
- IRC 501(c)(3).

State Laws

- State antikickback laws—may be broader than the federal law.
- Fee splitting—may prohibit a physician from sharing revenues with nonphysicians, and/or physicians outside of the group except on the basis of work performed, but may not apply.
- Many states require disclosure. Some specify how. Better to over disclose.



What Is Fair Market Value (FMV): Stark

- ***Fair market value*** means:
 - (1) ***General***. The value in an arm's-length transaction, consistent with the general market value of the subject transaction.
 - (2) ***Rental of equipment***. With respect to the rental of equipment, the value in an arm's-length transaction of rental property for **general commercial purposes (not taking into account its intended use)**, consistent with the general market value of the subject transaction.
 - (3) ***Rental of office space***. With respect to the rental of office space, the value in an arm's-length transaction of rental property for **general commercial purposes (not taking into account its intended use)**, without adjustment to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee, and consistent with the general market value of the subject transaction.

42 CFR §411.351

Compensation Revisited

- You sign a lease in 2006. The market crashes in 2008. How soon must you reassess the market value of the property?
- A physician group enters a PSA with the hospital for 5 years. Must the compensation be re-evaluated every year? Every two years? Every three?

General Market Value

- General market value means:
 - (1) Assets. With respect to the purchase of an asset, the price that an asset would bring **on the date of acquisition** of the asset as the result of bona fide bargaining between a well-informed buyer and seller that are not otherwise in a position to generate business for each other.
 - (2) Compensation. With respect to compensation for services, the compensation that would be paid **at the time the parties enter into the service arrangement** as the result of bona fide bargaining between well-informed parties that are not otherwise in a position to generate business for each other.
 - (3) Rental of equipment or office space. With respect to the rental of equipment or the rental of office space, the price that rental property would bring **at the time the parties enter into the rental arrangement** as the result of bona fide bargaining between a well-informed lessor and lessee that are not otherwise in a position to generate business for each other.

42 CFR §411.351

Beware Of The Trick Question

Commercially Reasonable

- *Commercially reasonable* means that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. **An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties.**

42 CFR §411.351

How Is Compensation Sliced?

- 42 CFR §411.354(c)(2)(ii) states that indirect compensation arrangements examine “**aggregate** compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship.”
- Compensation is considered in its entirety (aggregate).
- There is no temporal demarcation.

“We Have No Contract For Dr. Bowie’s Call”

- Question the premise. What constitutes a “written contract?”
- Changes to Stark in 2020 are very helpful.
- “Writing” can be satisfied by a collection of documents, including contemporaneous documents.
- Signature requirement can be satisfied by an electronic or other signature valid under Federal OR State law.
- Signatures obtained within 90 days are adequate.
- Don’t forget the new limited remuneration exception.

§411.354(e)
Fredrikson

Limited Remuneration: 42 C.F.R. 411.357(z)

- Permits compensation up to \$5,000 per calendar year, adjusted for inflation.
- Compensation can't take into account volume and value of referrals/other business, can't exceed FMV, must be commercially reasonable absent referrals, and, if a lease, not per click.
- If remuneration is conditioned on referrals, must meet 411.354(d)(4).
- Applies to employees and locum physicians.
- One bummer: you can't "stack" physicians. For a group of 10, the cap is still \$5,000, not \$50,000.

What Constitutes Evidence?

- Informal communication via email or text.
- Internal notes to file.
- Similar payments between the parties from prior arrangements.
- Generally applicable schedules.
- Other documents recording similar payments to or from other similarly situated physicians for similar services.

85 FR 77492, 77592

Changes To Dr. Bowie's Contract...

- “Compensation (or a formula for determining the compensation) that is modified at any time during the course of a compensation arrangement, including the first 90 days of the arrangement, satisfies the set in advance requirement of various exceptions only if all of the following conditions are met —
- Prospective changes are permissible as long as they still meet the Stark exception.

85 F.R. 77594

Let's Talk Bowie's Records

- Stark doesn't explicitly require time records.
- Clearly having them is useful.
- Your agreement can impose a higher burden than the law. Is a detailed agreement always helpful???

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