Health Law 101

October 12, 2022

Fredrikson & BYRON, P.A.

Our Agenda

- Basics of Health Law Research and the Administrative Hierarchy: 8 minutes
- Intro to Medicare and Medicaid: 5 minutes.
- Antikickback/Stark/Beneficiary Inducement: 25 minutes
- Medicare's 60 day Rule: 5 minutes
- Introduction to Medical Staff Issues: 10 minutes
- Antitrust/Certificate of Need: 7 minutes
- Licensing Boards and Key Medical Malpractice and Risk Management Issues: 15 minutes
- Tips for Responding to Government Investigations: 7 minutes

Preliminary Thoughts

- Who do you believe?
- There are more laws than we can cover in a pair of webinars.
- “Fraud” is a policy tool.
- Never forget state law.

Conceptualizing The Law

- Laws affecting relationships.
- Laws detailing billing methodology.
- Think of Fruit Loops!

Conceptualizing The Law

- Laws affecting relationships.
- Laws detailing billing methodology.
- Two cans: Can we do it vs. Can we bill for it?
- Whose rule?
- Payor variability: Is discrimination ok?
- Contract vs. Law.

Conceptualizing The Law

- Note the Medicare legal hierarchy.
  - Constitution, statute, regulation, NCD.
  - LCD, preamble, manual, LCD, 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???)

Research Strategies

Hierarchy Of Authority

- Constitution (due process, contracts clause, enumerated powers).
- Statutes (Social Security Act).
- Regulations (42 CFR).
- National Coverage Determinations.
- Local Coverage Determinations.
- Program guidance (manuals, bulletins, FAQs, regulatory preambles).

Sources Of Authority??

- OIG Work Plan.
- Contractor publications.
- Trade group statements.
- Law firm/consultant newsletters/webinars.

What Are The Medicare Manuals?

- Sub-regulatory guidance.
- CMS's instructions for administration of the Medicare program.
- Examples:
  - Medicare Claims Processing Manual.
  - Medicare Benefit Policy Manual.
  - National Coverage Determinations Manual.

Manuals/Guidance Cannot Limit Coverage

42 U.S.C. § 1395hh(a)(1) says nothing other than an NCD may change benefits unless promulgated as a regulation.

42 U.S.C. § 1395hh

(a)(2) No rule, requirement, or other statement of policy (**other than a national coverage determination**) that establishes or changes a substantive legal standard governing . . . the payment for services . . . under this subchapter shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1).

U. S. Department of Justice

Office of the Associate Attorney General

The Associate Attorney General

Washington, D.C. 20530

January 25, 2018

MEMORANDUM FOR: HEADS OF CIVIL LITIGATING COMPONENTS
UNITED STATES ATTORNEYS

CC: REGULATORY REFORM TASK FORCE

FROM: THE ASSOCIATE ATTORNEY GENERAL

SUBJECT: Limiting Use of Agency Guidance Documents
In Affirmative Civil Enforcement Cases

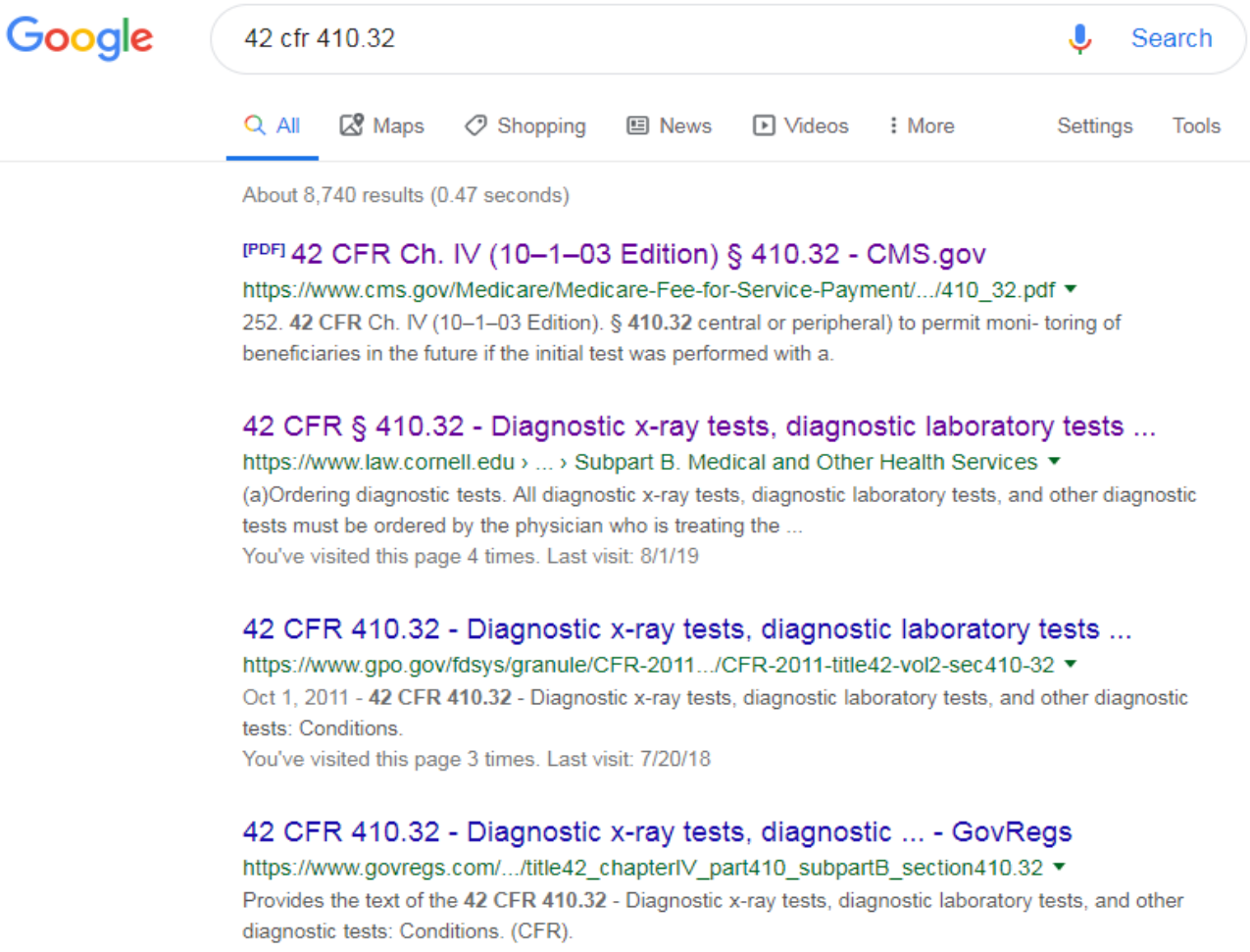
On November 16, 2017, the Attorney General issued a memorandum ("Guidance Policy") prohibiting Department components from issuing guidance documents that effectively bind the public without undergoing the notice-and-comment rulemaking process. Under the Guidance Policy, the Department may not issue guidance documents that purport to create rights or obligations binding on persons or entities outside the Executive Branch (including state, local, and tribal governments), or to create binding standards by which the Department will determine compliance with existing statutory or regulatory requirements.

The Guidance Policy also prohibits the Department from using its guidance documents to coerce regulated parties into taking any action or refraining from taking any action beyond what is required by the terms of the applicable statute or lawful regulation. And when the Department issues a guidance document setting out voluntary standards, the Guidance Policy requires a clear statement that noncompliance will not in itself result in any enforcement action.

Manuals/Guidance Cannot Limit Coverage

- "Thus, if government manuals go counter to governing statutes and regulations of the highest or higher dignity, a person 'relies on them at his peril.' " Government Brief in Saint Mary's Hospital v. Leavitt.
- "[The Manual] embodies a policy that itself is not even binding in agency adjudications…. Manual provisions concerning investigational devices also 'do not have the force and effect of law and are not accorded that weight in the adjudicatory process.' " Gov't brief in Cedars-Sinai Medical Center v. Shalala.

Google With Caution!



Google With Caution!

[PDF] 42 CFR Ch. IV (10–1–03 Edition) § 410.32 - CMS.gov

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/.../410_32.pdf

252. **42** CFR Ch. IV (10–1–03 Edition). § **410.32** central or peripheral) to permit moni- toring of beneficiaries in the future if the initial test was performed with a.

Google With Caution!

central or peripheral) to permit monitoring of beneficiaries in the future if the initial test was performed with a technique that is different from the proposed monitoring method.

(d) *Beneficiaries who may be covered.* The following categories of beneficiaries may receive Medicare coverage for a medically necessary bone mass measurement:

(1) A woman who has been determined by the physician (or a qualified nonphysician practitioner) treating her to be estrogen-deficient and at clinical risk for osteoporosis, based on her medical history and other findings.

(2) An individual with vertebral abnormalities as demonstrated by an x-ray to be indicative of osteoporosis, osteopenia, or vertebral fracture.

(3) An individual receiving (or expecting to receive) glucocorticoid (steroid) therapy equivalent to 7.5 mg of prednisone, or greater, per day for more than 3 months.

(4) An individual with primary hyperparathyroidism.

(5) An individual being monitored to assess the response to or efficacy of an FDA-approved osteoporosis drug therapy.

sonable and necessary (see § 411.15(k)(1) of this chapter).

(1) *Chiropractic exception.* A physician may order an x-ray to be used by a chiropractor to demonstrate the subluxation of the spine that is the basis for a beneficiary to receive manual manipulation treatments even though the physician does not treat the beneficiary.

(2) *Mammography exception.* A physician who meets the qualification requirements for an interpreting physician under section 354 of the Public Health Service Act as provided in § 410.34(a)(7) may order a diagnostic mammogram based on the findings of a screening mammogram even though the physician does not treat the beneficiary.

(3) *Application to nonphysician practitioners.* Nonphysician practitioners (that is, clinical nurse specialists, clinical psychologists, clinical social workers, nurse-midwives, nurse practitioners, and physician assistants) who furnish services that would be physician services if furnished by a physician, and who are operating within the scope of their authority under State

Links To Official Versions

- Current CFR: https://gov.ecfr.io/cgi-bin/ECFR.
- Federal Register: https://www.federalregister.gov/.
- Manuals: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/index.html?redirect=/manuals/.

Pay Attention To Effective Dates

20.1.2.1 - Cost to Charge Ratios
(Rev. 2111, Issued: 12-03-10, Effective: 04-01-11, Implementation: 04-04-11)


POLICE

Time Traveling Manual

10 - Covered Inpatient Hospital Services Covered Under Part A
(Rev. 234, Issued: 03-10-17, Effective: 01-01-16, Implementation: 06-12-17)

Patients covered under hospital insurance are entitled to have payment made on their behalf for inpatient hospital services. (Inpatient hospital services do not include extended care services provided by hospitals pursuant to swing bed approvals. See Pub. *100-02*, Chapter 8, §*10.3*, "Hospital Providers of Extended Care Services."). However, both inpatient hospital and inpatient SNF benefits are provided under Part A - Hospital Insurance Benefits for the Aged and Disabled, of Title XVIII).

Additional information concerning the following topics can be found in the following chapters *of this manual*:

- Benefit Period is found in Chapter 3
- *Counting Inpatient* Days is found in Chapter *3*
- Lifetime reserve days is found in Chapter 5
- Related payment information is housed in the Provider Reimbursement Manual

Blood must be furnished on a day which counts as a day of inpatient hospital services to

U.S. ex rel. Dunn v. North Memorial Health

- Relator alleged that certain supervision and documentation requirements for pulmonary and cardiac rehab services had not been met.
- But the regulation creating these requirements did not go into effect until after the relevant time period!

Is The Manual Up-To-Date?

Medicare Claims Processing Manual

Chapter 3 - Inpatient Hospital Billing

Table of Contents

(Rev. 4337, 07-18-19)

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 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)

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 Circ. 2019).

Medicare 101

- Mostly over 65, also disability.
- Medicare Part A (providers) vs. Part B (suppliers), Part C (Medicare Advantage) and Part D (Drugs).
- CMS Baltimore/Regional Offices.
- Medicare Administrative Contractors.

Medicare Advantage

- While “Medicare” is in the name, it is more like a private insurer.
- Some rules, like Stark, and the False Claims Act, may still apply.
- Most reimbursement rules do NOT.
- Medicare Advantage must provide coverage at least as generous as Medicare.

Key Players

- Center For Medicare and Medicaid Services (CMS).
- Office of Inspector General (OIG).
- Medicare Administrative Contractors (MACs).
- State Agencies (SA).

Medicare 101

- Understand if reimbursement is fee for services (FFS), prospective payment (PPS) or something else.
- Beware of the “combo.” DRG is prospective, but don’t forget outliers.
- Professional and technical components, facility fees. Graduate medical education.

Names Matter

- Part A: Providers (42 CFR 400.202):
  - Hospital.
  - CAH.
  - SNF.
  - CORF.
  - HHA.
  - Hospice.
  - Rehab agency to furnish PT or SLP.
  - CMHC to furnish PHP.

Names Matter

- Part B: Suppliers (42 CFR 400.202):
  - Physician.
  - Other practitioner.
  - “Entity other than a provider that furnishes health care services under Medicare.”
    - IDTF (Independent Diagnostic Treatment Facility
    - DMEPOS (Durable Med. Equip. Prosthetics/Orthotics Supplies)
    - ASC (Ambulator Surgical Center)
    - Clinic

Billing Differences

- Part A:
  - Typically on a UB-04.
  - Likely to be prospective (but may be cost based, like critical access hospital).
- Part B:
  - Typically on a 1500.
  - Typically on a fee schedule.

One Event, Two Bills

- Patient presents in the ED.
- Physician's professional component billed on a 1500, listing a "Place of Service" outpatient hospital.
- Hospital facility fee on a UB-04.
- Note that the "levels of service" may differ!

Location, Location, Location?

- Does place of service matter?
- Hospital vs. Clinic? Yes.
- Clinic vs. Urgent Care? Probably not.

Cost Reports

- Largely an artifact of cost-based reimbursement.
- Used to gather data to set reimbursement rates.
- Establishes “cost-to-charge” ratio, or CCR.
- Service costs $90, fee is $100, CCR=.9

Medicaid 101

- Generally low income or disability.
- Combined state/federal.
- Rules are state driven.
- Increasingly involves managed care.
- Federal reporting requirements:
  - 42 CFR Part 455 (Medicaid Program Integrity)

Key Players

- State Agency.
- Surveillance and Utilization Review (SURS).
- Medicaid Fraud Control Unit (MFCU).
- OIG (Federal and perhaps state).
- State AG.

Private Insurance

- Is there a contract?
- If not, industry norms control.
- If yes, the terms control. Does it incorporate a manual?
- Don’t forget state law, which may prevent the insurer from doing what it wants!

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…")

Trouble?

- Hospital provides a physician a medical directorship without expecting actual work.
- A physician plays two hospitals off of one another saying, “If you don’t give us this, we will take our business to the other hospital.”
- Can a physician demand faster OR turn-around?

Advisory Opinions

- Must be a serious proposal.
- Must disclose parties and facts.
- Must pay government's costs.
- OIG will not analyze fair market value.
- Only binding for the parties involved.
- Generally, advisory opinions do not give you much security.

ABCs Of ASCs: How Not To Get Conned

- Four safe harbors:
  - Surgeon-owned ASCs.
  - Single-specialty.
  - Multi-specialty.
  - Hospital physician.

Important Principle

"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.


DANGEROUS SHOREBREAK
IF IN DOUBT, DON'T GO OUT
WARNING
STRONG CURRENT
YOU COULD BE SWEPT AWAY FROM SHORE AND COULD DROWN
IF IN DOUBT, DON'T GO OUT
WARNING
POLOLU TRAIL
WARNING
Hazardous Cliff!
The ground may break off without warning and you could be seriously injured or killed.
Stay back from the edge.
DO NOT APPROACH MONK SEALS

Civil Monetary Penalty Provision

- The CMP law SSA § 1128A(a)(5) and the anti-kickback statute SSA § 1128B(b) are different.
- CMP includes anything "that the benefactor knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of any item or service." Limited to beneficiaries!
- Anti-kickback exceptions protect under CMP, but not vice-versa.

Stark

- Applies only to DHS, but all hospital services are DHS. (See next slide for others.)
- If any value flows between a physician and an "entity" and the physician orders DHS provided at the entity, Stark applies.
- Intent doesn't matter; you must meet every part of an exception.
- Not criminal; but the penalty is up to $15,000/claim.

“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 outpatient hospital services.

Stark Is Yucky

- It is much harder to do a Stark analysis.
- Stark only applies if a physician orders services covered by Medicare or Medicaid that are:
  - Designated Health Services (DHSs) AND
  - Provided by whoever has a financial relationship with the doctor.

Stark Quirks

- The offending financial relationship may be unrelated to the referrals. (Lawn mowing.) They can be hard to find.
- "Referral" is making a plan of care.
- The "entity" includes both:
  - The entity billing for the service AND
    The entity providing the service.
  - This prohibits "under arrangements" relationships if the physician who orders the service is providing it "under arrangements."
  - If a physician is leasing equipment to a hospital, and sending patients to the equipment, beware.

Exceptions That Protect Both Ownership And Compensation

- Physician services.
- In-office ancillary services.
- Prepaid plans.
- Electronic prescribing.

Ownership Exceptions

- Investment in publicly traded securities/mutual funds.
- Hospitals in Puerto Rico.
- Rural providers. (Outside an MSA.)
- Hospital ownership (note the time limit).

Compensation Exceptions

- Rental of office space or equipment.
- Bona fide employment.
- Personal service arrangements.
- Remuneration unrelated to the provision of DHS.
- Physician recruitment.
- Isolated transactions.
- Certain group practice arrangements with the hospital (must pre-date 12/19/89).

Compensation Exception: Often Overlooked

- Payments by a physician for items and services “to an entity as compensation for other items or services if the items or services are furnished at a price that is consistent with fair market value.”

Key Principles

- With few exceptions (employment), agreements must be written.
- Amendments must be written as well.
- Use auto-renewal terms!
- FMV is usually important.

Antikickback v. Stark

Antikickback.

- Criminal.
- Civil monetary penalties/exclusion.
- Intent is everything.

Stark.

- Civil.
- $15,000 per claim/ $100,000 for circumvention scheme (fines apply only if bills are submitted).
- Intent is irrelevant.

Antikickback v. Stark

- If you meet a safe harbor, you win. If you do not meet a safe harbor, analyze intent.
- Only applies to relationships outside the corporation.
- Must meet an exception, or else.
- Applies to both transactions with others and intra-organization relations, including your compensation formula.

Antikickback v. Stark

- Covers everything paid for by a federal health care program (beware of state law extensions).
- Can get advisory opinion.

- Covers only designated health services paid by Medicare or Medicaid (but note definition of group practice).
- Can get advisory opinion.

Non-Profit/Tax Exemption Issues

- "Private inurement/private benefit" 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.

Sunshine Act

- All transfers of value (over $10) from device companies to physicians must be reported.
- Look out for state sunshine laws that extend beyond physicians.

Getting Concrete

- Device rep really wants a physician's advice. Offers to pay $200/hour if physician will attend a focus group at the Ritz in NYC.
- Analysis: Stark, Antikickback, tax exemption, ethics.

Stark Analysis

- Does the device company bill Medicare or Medicaid for drugs prescribed by the physician?
  - Probably not. Most likely the billing is done by a hospital or some other entity, so Stark is inapplicable.

Antikickback Analysis

- Is there an argument that the device manufacturer is paying the physician to influence referrals paid for by a federal health care program?
  - Yes.

Antikickback Analysis

- What exactly is the physician being paid for?
- Why The Ritz in NYC? Could the same thing be done in the physician's office? Via teleconference? In Ottumwa?
- "Live from the airport, for Fox Nine News."
- This is also where ethics creep in.

State Law Analysis

- Antikickback statute.
- State disclosure laws.

“It’s Not A Conflict If I Disclose It!”

- Physician owns a company providing per-click diagnostic services to the hospital.
- Physician says, “We tell every patient so it is ok.”

Food, Fun and Friends

- An orthopod and a family practitioner are good friends. The ortho takes the family practitioner to the best restaurant in town to celebrate the family practitioner's birthday.
- The total bill is $350.

Food, Fun, Friends and Felony?

- An orthopod and a family practitioner are good friends. The ortho takes the family practitioner to the best restaurant in town to celebrate the family practitioner's birthday.
- The total bill is $100.
- The ortho submits the receipt to his clinic as a promotional expense.

Muddled Thinking

You buy devices wholesale and bill insurers for them. The device manufacturer tells you, “If you buy 10, they cost $1,000 each. If you buy 100, they are yours for $800. For each one you buy after that, there is a $100 rebate.”

Muddled Thinking

- This deal will cause most people to blanch. But there is nothing wrong with it unless you:
  - Are paid on a cost basis, AND
  - Fail to accurately state the price by disclosing the discount.

"You Can't Charge For Something You Got For Free"

- Catchy. Sounds true. Oft repeated.
- Think about it. If you pay a penny for something, is there a limit on your ability to mark it up? (There is for diagnostic test. And drug samples.)
- "Free" and "cheap" are analytically the same.

Fee Splitting

- May prohibit a physician from sharing revenues with non-physicians, and/or physicians outside of the group except on the basis of work performed.
- May be in ethical rules.
- Unusual interpretations can prohibit percentage management contracts. (See Florida).
- Notice to patients?

If You See Something Say Something? 60 Day Rule

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

SSA § 1128J

GENERAL.—If a person has received an overpayment, the person shall—

(A) **report and return** the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address; and

(B) notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.

SSA § 1128J

An overpayment must be reported and returned under paragraph (1) by the later of—

(A) the date which is 60 days after the date on which the overpayment was identified; or

(B) the date any corresponding cost report is due, if applicable.

Overpayment

"*Overpayment* means any funds that a person has received or retained under title XVIII of the Act to which the person, *after applicable reconciliation*, *is not entitled under such title.**"

- 42 CFR 401.303

*This is important, but we will come back to it.

Applicable Reconciliation

"The applicable reconciliation occurs when a cost report is filed; and …"

- 42 CFR 401.305(c)

•Page 7668 includes a convoluted assertion that reconciliation is cost-report specific. The discussion refers to Parts A and B. Part B doesn't feature cost reports.

Applicable Reconciliation

"The applicable reconciliation occurs when a cost report is filed; and …"

- 42 CFR 401.305(c)

•Offsetting underpayments seems entirely consistent with the statute, and CMS' interpretation seems baseless.

How Far Back Must You Go?

- The law had no explicit temporal limits.
- If the government can't recoup the money, is it still an overpayment?

How Far Back Must You Go?

- Various statutory and regulatory provisions limited the government's ability to recoup money.
  - SSA 1870, 1879.
  - Reopening regulations.
- Our advice: Go back 48 months!!!

Medical Staff Basics

- Most of the lawyer's job is to read what and when others are not.
- Summer reading list:
  - Medicare Conditions of Participation (CoPs) for hospitals
  - Bylaws, rules and regulations, policies, and manuals
  - State hospital license act

Medical Staff Basics

- Summer reading list (cont.):
  - State peer review statute (and cases)
  - Health Care Quality Improvement Act (HCQIA)
  - National Practitioner Data Bank regulations and Guidebook
  - Applicable accreditation manual

What Is The Medical Staff?

- 42 CFR 482.22 “The hospital must have an organized medical staff that operates under bylaws approved by the governing body, and which is responsible for the quality of medical care provided to patients of the hospital.”
  - Must consist of MDs and DOs; may include non-physician practitioners.
- Governing body is legally responsible.

What is the Medical Staff?

- Performs significant functions of credentialing, privileging, and quality review.
- Conducts itself in accordance with the medical staff bylaws:
  - "A document or group of documents adopted by the voting members of the organized medical staff and approved by the governing body that defines the rights, responsibilities, and accountabilities of the medical staff and various officers, persons, and groups within the structure of the organized medical staff, the self-governance functions of the organized medical staff; and the working relationship with and accountability to the governing body of the organized medical staff."

Process, Process, Process.

- For credentialing and privileging, elections, and corrective action/fair hearing, process is key.
- Recall: state law that says the bylaws are an enforceable contract.
- State immunity and confidentiality of peer review.
- Health Care Quality Improvement Act of 1986 (HCQIA)

State Peer Review Laws

- Immunity for medical staff functions
  - Scope of immunity: what type of claim? Damages?
  - Who gets the immunity?
    - Witnesses? Governing body?
  - Must there be good faith?
  - Is it a protection or a privilege?
- Confidentiality requirements
  - What is confidential: documents? Discussions?
  - Who must maintain confidentiality?
  - Exceptions? (E.g., licensing boards, other hospitals)

Health Care Quality Improvement Act Of 1986

- 42 U.S.C. 11101 et seq.
- Federal law providing immunity for "professional review actions."
  - "Action or recommendation of a professional review body . . . which is based on the competence or professional of an individual physician."

Health Care Quality Improvement Act Of 1986

- Standards for immunity
  - Reasonable belief the action was taken in furtherance of quality healthcare
  - Reasonable effort to obtain the facts
  - Adequate notice and hearing procedures
  - Reasonable belief that action was warranted by the facts
- Rebuttable presumption the standards were met; must be overcome by a preponderance of the evidence.

National Practitioner Data Bank

- Created by HCQIA.
- Reporting obligations when there are certain adverse clinical actions.
  - Hospitals must report to NPDB
  - State licensing boards report to NPDB
  - NPDB reports to licensing boards and other facilities who have queried the data bank regarding the physician
- Failure to report properly jeopardizes HCQIA immunity.
- Read the Guidebook.

Medical Staff Wrap-up

- Know your bylaws.
- Know your state law.
- Remember HCQIA.
- Consult the NPDB Guidebook.

Antitrust: The Big Picture

- Policy: Competition is good.
- The Spice Girls on Health Policy.
- Do we want an MRI on every corner?
- The con of CON?
- **Biased heavily in favor of buyers.**
- Policy is almost as important as law.
- Antitrust is a broad term covering many behaviors.

Antitrust

Jon Liebowitz, Head of FTC:

> "If you fix prices – that is, if independent doctors jointly negotiate the fees they charge – we will make you stop. But, if you join together to improve patient care and lower costs, not only will we leave you alone, we'll applaud you."
>
> - June 14, 2010, remarks to the American Medical Association

A Single Entity Can't Conspire

- If you can be "one entity" you can't "conspire." U.S. Supreme Court American Needle Decision.
- But the act of becoming one entity can be problematic.
- Clinical or financial integration are possible defenses to certain antitrust issues.

Market Power

- For many antitrust issues, a violation is possible only if you have “market power.” The definition of the market is key.
  - Product Market: what other good/service can a buyer get instead?
  - Geographic Market: where could the buyer reasonably go for an alternative?

Geographic Market

- Is it dollars, practitioners, services?
- How do you get the data?
- How far will people go for health care?
  - Note, it is where they COULD go, not where they DO go
  - Type of care matters; chemo v. stent.

What Is The Most Dangerous Activity For Physicians?

"Psst . . . Quit taking insurance. Pass it on."

Antitrust Violations

- Price Fixing: competitors agree to sell at a price or establish a minimum price (you don’t need market power).
- Boycott: competitors agree not to deal with a particular party.

Antitrust Violations

- Monopolization: one party controls enough of the market to be able to fix price. Market share and barriers to entry are both relevant.
- Tying arrangements: one party requires buyers to purchase an unrelated item to receive the item sought by the purchaser (seller must have “market power”). But buyers can likely tie!

Antitrust

- Most of the antitrust laws (with the exception of monopolization) require agreement between competitors.
- Airline pricing/conscious parallelism.

Antitrust Practicalities

- If the payor is happy, not much matters.
- If the payor is unhappy, they often get more legal deference.
- Politics can, at times, trump law.

When Antitrust Matters

- Negotiations with insurers.
- Relations with hospitals.
- Peer Review.
- Joint ventures.
- Pricing.
- Mergers.

Licensing Boards

- Varies substantially by state.
- Governed by practice statute, rules, advisory opinions, informal guidance/
- Governs the practice of the profession:
  - Getting/renewing/surrendering a license;
  - Scope of practice/delegation/supervision;
  - Interstate issues and telemedicine; and
  - Discipline.

Legal Authorities

- Practice Act.
- Rules promulgated by the licensing board.
- Advisory opinions.
- Informal guidance on the website.
- Informal guidance provided via phone or email.

Licensing

- Licensing requirement (practice versus name).
- Licensing categories.
- Requirements for license:
  - Educational requirements;
  - Exams; and
  - Fees.
- Continuing education requirements.

Scope Of Practice—Definitions

Subd. 5. **Clinical nurse specialist practice.** "Clinical nurse specialist practice" means:

(1) the diagnosis and treatment of health and illness states;

(2) disease management;

(3) prescribing pharmacologic and nonpharmacologic therapies;

(4) ordering, performing, supervising, and interpreting diagnostic studies, excluding interpreting computed tomography scans, magnetic resonance imaging scans, positron emission tomography scans, nuclear scans, and mammography;

(5) prevention of illness and risk behaviors;

(6) nursing care for individuals, families, and communities;

(7) consulting with, collaborating with, or referring to other health care providers as warranted by the needs of the patient; and

(8) integration of care across the continuum to improve patient outcomes.

Delegation

(i) Aiding or abetting an unlicensed person in the practice of medicine, except that it is not a violation of this paragraph for a physician to employ, supervise, or delegate functions to a qualified person who may or may not be required to obtain a license or registration to provide health services if that person is practicing within the scope of that person's license or registration or delegated authority.

Subd. 2. **Delegated duties; prohibitions.** (a) A speech-language pathology assistant may perform only those duties delegated by a licensed speech-language pathologist and must be limited to duties within the training and experience of the speech-language pathology assistant.

(b) Duties may include the following as delegated by the supervising speech-language pathologist:

(1) assist with speech language and hearing screenings;

(2) implement documented treatment plans or protocols developed by the supervising speech-language pathologist;

(3) document client performance;

(4) assist with assessments of clients;

(5) assist with preparing materials and scheduling activities as directed;

(6) perform checks and maintenance of equipment;

(7) support the supervising speech-language pathologist in research projects, in-service training, and public relations programs; and

(8) collect data for quality improvement.

Supervision

20:52:01:03.01. Supervision of a licensed physician assistant. A licensed physician assistant shall be supervised by a physician licensed pursuant to SDCL chapter 36-4. The supervising physician shall be available for consultation with the physician assistant at all times while the physician assistant is involved in patient care. The supervising physician and physician assistant shall meet to discuss patient care and review the physician assistant practice. The supervision plan shall be outlined in the practice agreement and approved by the board.

Interstate Issues

- Generally, a local license is required.
- Common exceptions:
  - Emergencies;
  - Consults with local professionals; or
  - Irregular services provided to established patients.
- Reciprocal arrangements.
- COVID waivers.

Telemedicine

- Two issues:
  - Quality of remote services (e.g., type of technology that must be used, in-person exam requirements).
  - Interstate issues (when patient and physician are in different states).
- Statutes, rules, or guidance may address these issues.

Discipline

- The Board has authority to discipline professionals, including the power to revoke or suspend a license.
- Common grounds for discipline:
  - Unlicensed practice.
  - Poor quality of care or scope of practice.
  - Fraud and abuse.
  - Substance abuse.
  - Inappropriate conduct with patients.
  - Catch-all.

Discipline

- A professional has a constitutionally protected interest in her state-issued license.
- Due process protections will apply—notice of the allegations and an opportunity to be heard.
- Settlements or stipulations are common.

Malpractice

- Elements of malpractice:
  - Existence of a professional-patient relationship.
  - Breach of the standard of care.
  - Causation.
  - Damages (pain/suffering, emotional distress, medical costs, lost earnings/income capacity).

Malpractice “Flavors”

- Improper treatment.
- Failure to diagnose.
- Inadequate consent.
  - Consent wasn’t informed (failure to warn).
  - Consent wasn’t obtained (battery).

Common Malpractice Defense Strategies

- Procedural defenses.
- Establish a favorable standard of care via expert evidence.
- Challenge the causal link between the alleged malpractice and the alleged damages.
- Chip away at the damages.

Practical Tips

- Good communication with patients at the bedside reduces the risk.
- Report claims promptly to your carrier.
- Use your peer review process!

Beware Of:

- Personalized correspondence.
- Medicare bulletins.
- Overpayment letters.
- Frequent denials.
- “Routine audit”/survey.

Office of Audit Services
Region I
John F. Kennedy Federal Building
Boston, MA 02203
(617) 565-2684

[redacted]

Dear Dr.

The Office of Inspector General of the Department of Health and Human Services is currently conducting an audit of payments for clinical laboratory services under the Medicare program. In this regard, we need your assistance to confirm that you (1) requested the services provided and billed to the Medicare program by a laboratory and (2) received and considered the test results in the treatment of your patient. Your response will be vital in assisting our efforts to ensure that Medicare dollars are appropriately spent on deserving beneficiaries.

As part of this audit, we are reviewing Medicare payments to laboratories for additional automated hemogram indices that were billed with hematology profiles (CBCs or other hematology profiles). Examples of additional automated hemogram indices include red cell distribution width (RDW), mean platelet volume (MPV), red blood cell histogram, platelet histogram and white blood cell histogram. These indices are in addition to the "standard" indices which are part of a CBC: the mean corpuscular volume (MPV), the mean corpuscular hemogolbin (MCH), and the mean corpuscular hemoglobin concentration (MCHC).

1. **Did you order a complete blood count (sometimes referred to as a "CBC") or other hematology profiles for this patient on this date?**

_____Yes _____No

2. **Did you specifically request any of the additional automated hemogram indices referenced above for this patient on this date?**

_____Yes _____No

4. If you answered "No" to question 2, please answer questions 4a through 4e below.

4a. Did you receive the additional automated hemogram indices as part of the test result provided from the laboratory?

____Yes _____No

4b. Were the additional automated hemogram indies routinely provided as part of your request for the hematology profiles?

_____Yes _____No _____Not Applicable

4c. Did the laboratory notify you that these additional automated hemogram indices were automatically included as part of hematology profiles?

_____Yes _____No _____Not Applicable

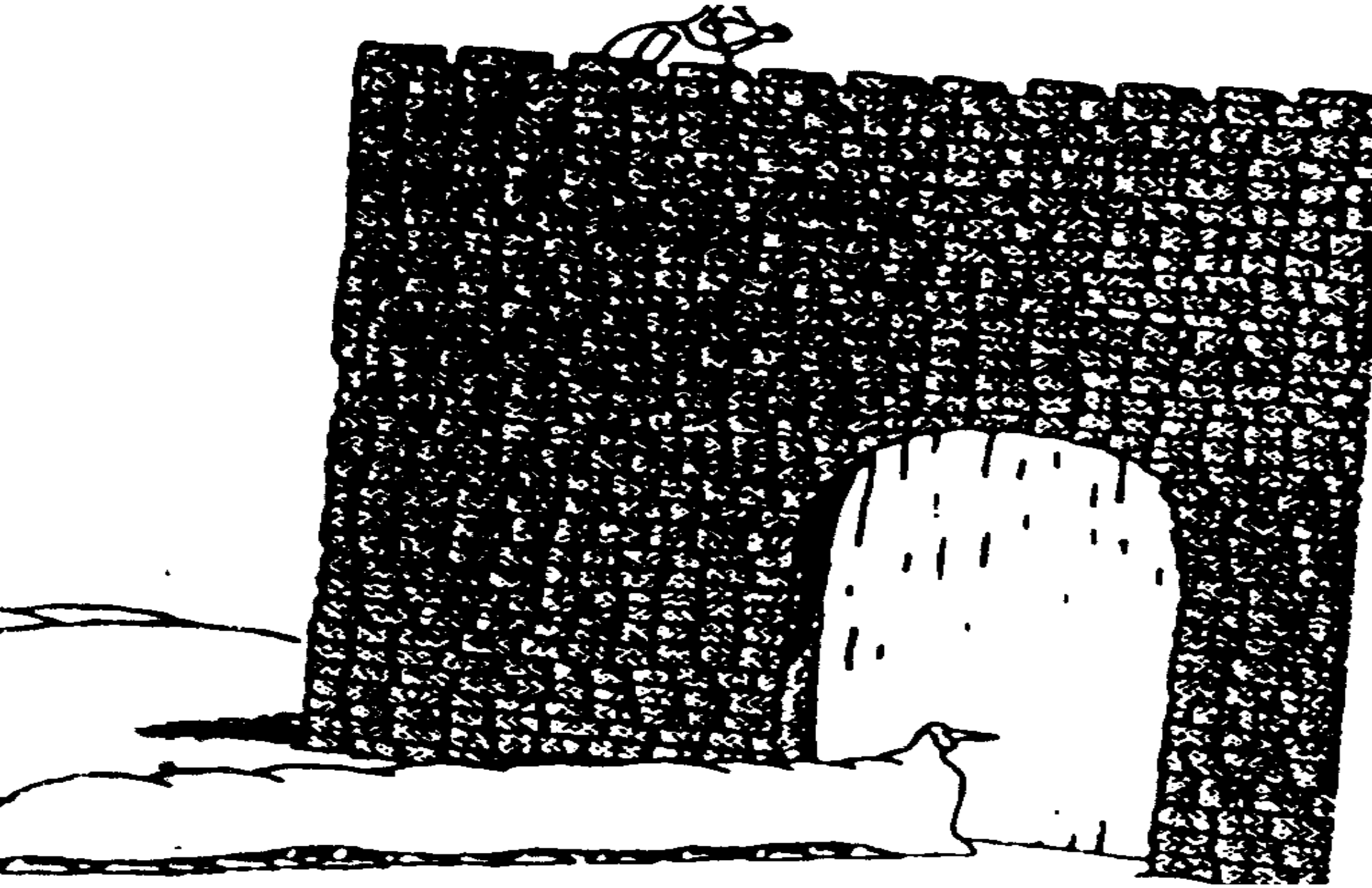
4d. Were you aware that these additional automated hemogram indices or other indices were billed separately under the Medicare program?

_____Yes _____No _____Not Applicable

4e. If you received the additional automated hemogram indices as part of the laboratory results, were the indices useful to you in the treatment of the Medicare patient?

_____Yes _____No _____Not Applicable

NOTE: If available, please provide an example copy of the laboratory requisition form.



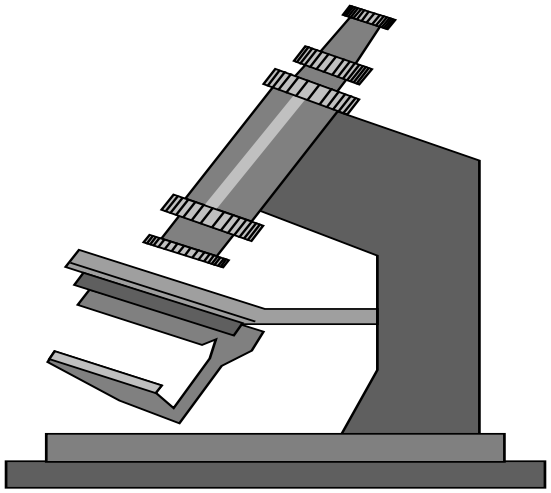
“Open the gate! It’s a big weiner dog!”

Beware of:

- Contact from the carrier or OIG.
- Sudden delays in reimbursement.
- Complaints from patients.
- Complaints from employees.

You're Under The Microscope If:

- Medicare requests multiple medical records. (Don't worry about individual prepayment reviews.)
- You receive an overpayment letter.
- The carrier or Office of Inspector General contacts you with specific questions or seeks a meeting.
- Armed agents pop up at employees' homes (or maybe office).



Prep Work Is Key

- You need to inoculate your employees.
- The half life of the vaccine is very, very short.
- An emergency plan must include how to contact people at odd hours.

The Subpoena

- You get a grand jury subpoena from Atlanta that says “The United States Attorney requests that you do not disclose the existence of this subpoena. Any such disclosure would impede the investigation being conducted and thereby interfere with the enforcement of the law."

The Letter

- Who sent it?
- Requests for multiple records are much more troubling.
- Make sure you keep a copy of everything you send.
- Be thorough.
- Talk with counsel.

The On-site Visit

- Keep track of what is reviewed.
- Keep the auditor isolated from the rest of the business.
- Be friendly, but firm.
- Try to be sure that no originals are altered.
- The terrifying DME story.

Telephone Calls

- Get the caller's name.
- Find out what they are talking about.
- Call the person back. This will allow you to verify the caller's identity, and gather your thoughts.

Armed Agents at the Door

- If they have a warrant, let them in.
- Do not talk to them.
- Get I.D. and call a lawyer.


KO
POP

The Courageous Nurse Alex Wubbels

- She stood her ground.
- She stayed calm.
- Good policies in place. She knew where to find them!
- She realized you can’t unring the bell. An important question: What permanent harm is done waiting for an answer?

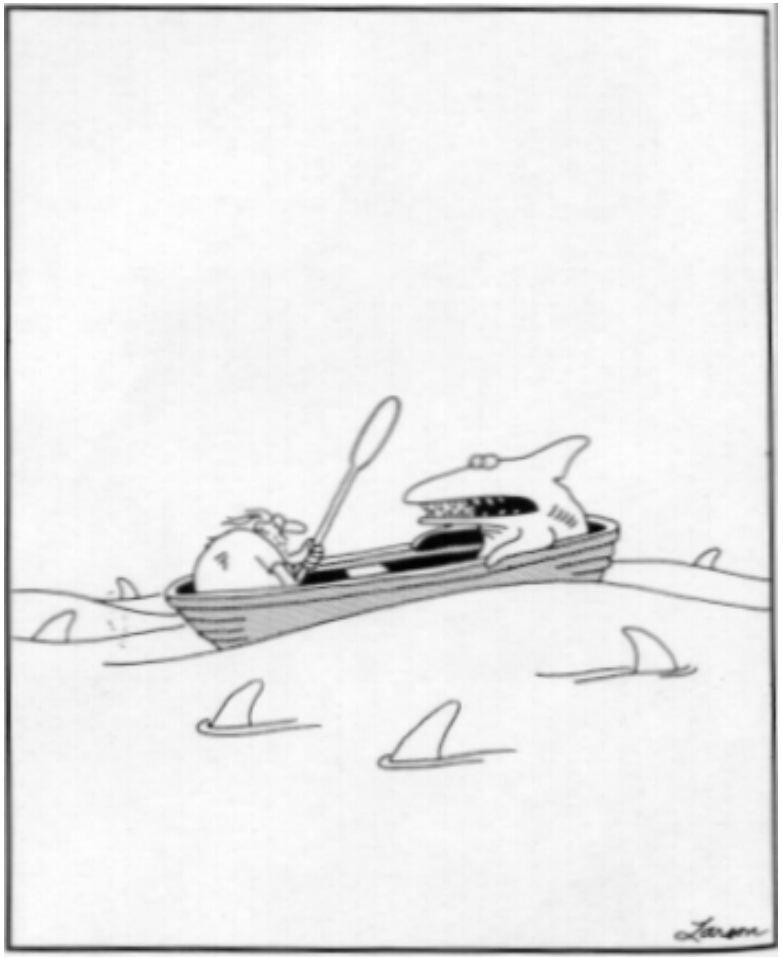
What Else Could Have Been Done?

- Video the encounter. (That is often resisted by officers, BUT IT IS ABSOLUTELY 100% LEGAL.)*
- Contact general counsel.
- As it escalates, bystanders can intervene/contact others.

*Maybe not in AZ???

Dealing with Investigations

- Agents want you to talk. They will use your:
  - Fear.
  - Confidence.
- Your biggest weapon:
  - Silence.
- Be especially wary of saying “My lawyer told me it was ok.” You will have waived the attorney-client privilege.



"OK. I'll go back and tell my people that you're staying in the boat, but I warn you they're not going to like it."

The Agents Are Not Your Friends:

- Don’t try to convince the agent, “It is all a misunderstanding.”

Remember two key points:

- Medicare rules are complicated. You may have violated one without knowing it.
- To many investigators - there is no such thing as an “innocent mistake.”

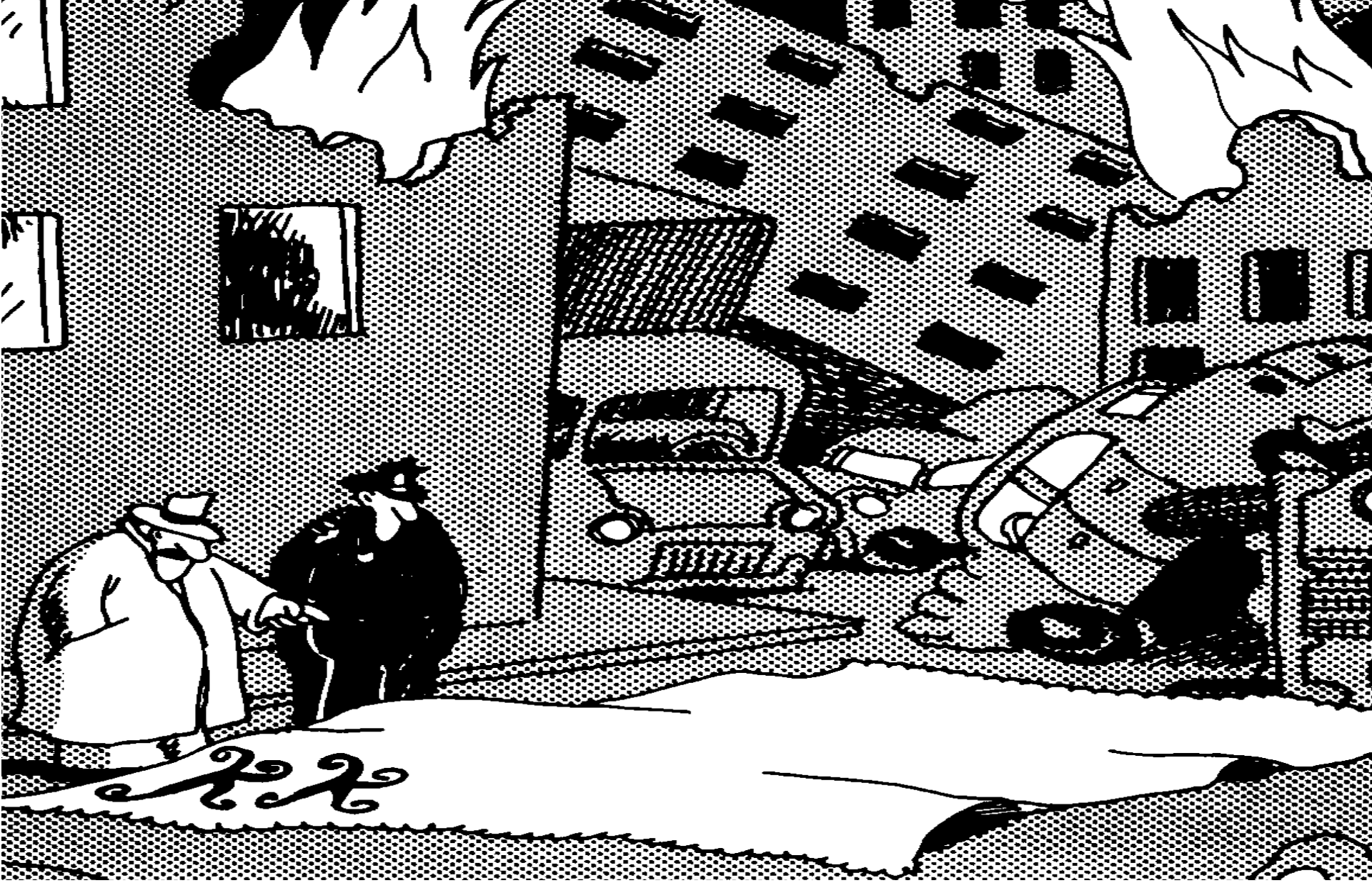
Know Your Rights

Agent:

- Cannot require anyone to attend interview.
- Cannot obtain documents without a warrant or subpoena.
- Cannot obtain privileged information.
- Cannot prevent you from talking about the interaction.

Know Your Obligations:

- Cannot prevent employees from talking.
- If you talk, you must tell the truth.
- Never destroy/hide documents.



“Take this handkerchief back to the lab, Stevens. I want some answers on which monster did this - Godzilla? gargantua? Who?”

Questions?

David Glaser
dglaser@fredlaw.com
(612) 492-7143

Pari I. McGarraugh
pmcgarraugh@fredlaw.com
612.492.7480

Katherine B. Ilten
kilten@fredlaw.com
612.492.7428