

# Health Law 101

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**Fredrikson**  
**& BYRON, P.A.**

# Our Agenda

- Antitrust/policy.
- False Claims Act.
- Stark.
- Medicare Antikickback Statute.
- Tax exemption.
- Incident to.
- Fee Splitting.
- Corporate Practice of Medicine.
- Two midnight rule.
- Provider-based billing.

# Preliminary Thoughts

- Who do you believe?
- There are more laws than we can cover in an hour.
- Whose ox is next to be gored?  
(Bundled payments?)
- What will be labelled as “fraud?”
- Never forget state law.

# Conceptualizing the Law

- Laws affecting relationships.
- Laws detailing billing methodology.
- Can we do it vs. Can we bill for it?
- Payor variability: Discrimination ok?
- Note the legal hierarchy.
- Not all laws are criminal.
- Some are counter-intuitive/contradictory.

# Tell Me What You Want, What You Really, Really Want

- Integration/consolidation.
- Avoiding redundancy (too many MRIs).
- Centralized planning/CON.
- Competition.
- Open markets.
- Innovation.

# False Claims Act: FCA

- Civil War statute, updated in the 1980s.
- Federal law allowing penalties of treble damages plus \$5,500-\$11,000 per claim. New rules increase the penalty to \$10,781/\$21,563
- Most states now have state laws.
- Requires some type of intent and materiality.
  - Is every mistake a false claim?
  - Is a dating error? 100 dating errors?

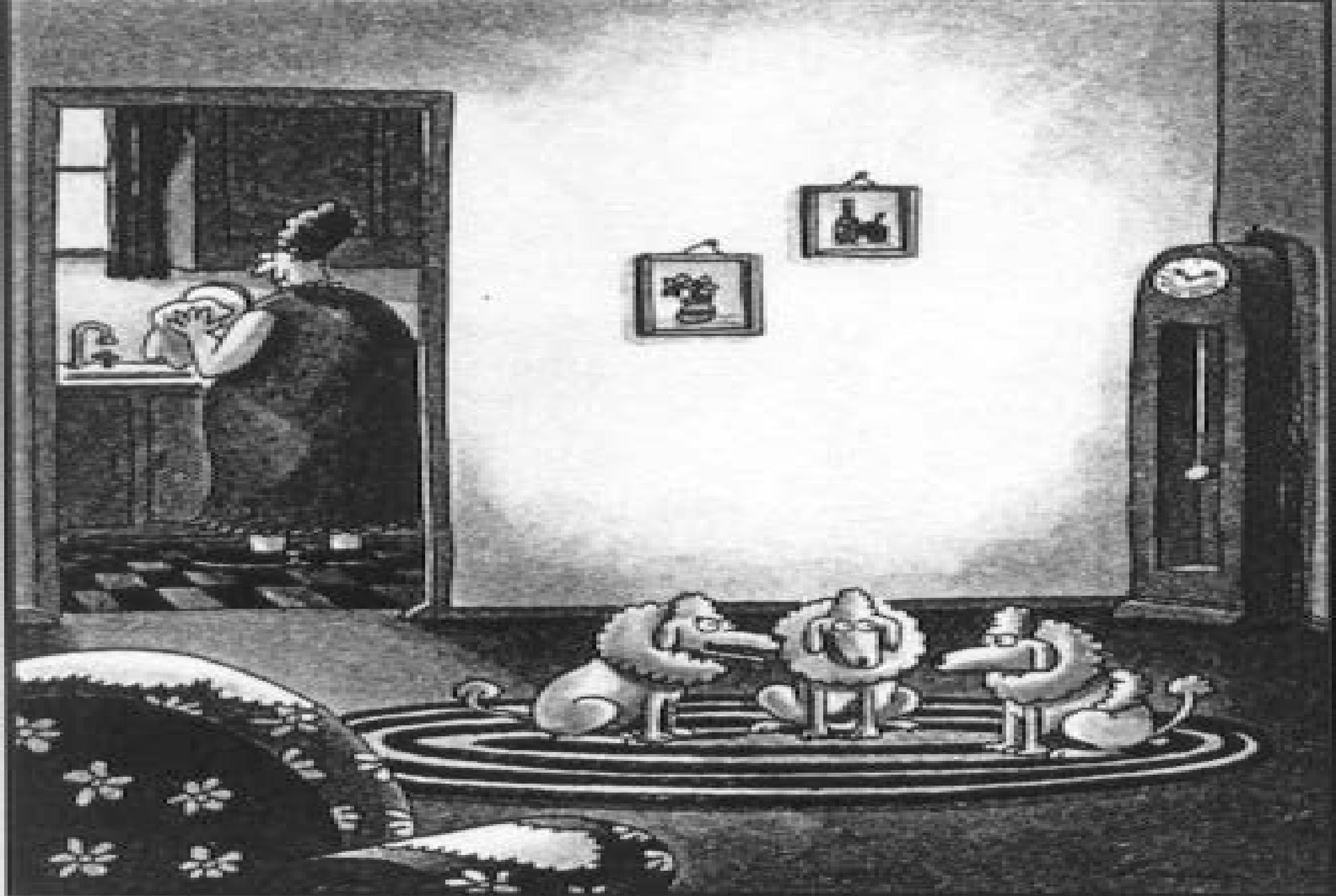
# Mistakes Are Not Fraud

- “Finally, the Guidance reaffirms that the False Claims Act should be the basis for suit only where there is evidence that false claims were submitted knowingly—that is, with actual knowledge or in deliberate ignorance or reckless disregard of the truth. Let me make this VERY clear: the False Claims Act does not address—and we should never use it to pursue—honest billing mistakes or mere inadvertence.”

Remarks of then Deputy Attorney General Eric H. Holder, Jr. to the American Hospital Association, February 1, 1999, *available at* <http://www.usdoj.gov/archive/dag/speeches/1999/holderahaspeech.htm>

# Qui Tam

- “Qui tam pro domino rege quam pro si ipso in hac parte sequitur.”
- Literally, means “who sues on behalf of the King as well as for himself.”
- A private attorney general, or bounty hunter statute.
- If victorious, plaintiff receives between 15 and 30% of the verdict, plus attorney fees.



“Well, yes, that is the downside, Fluffy. . . . When we kill her, the pampering will end.”

# Qui Tam

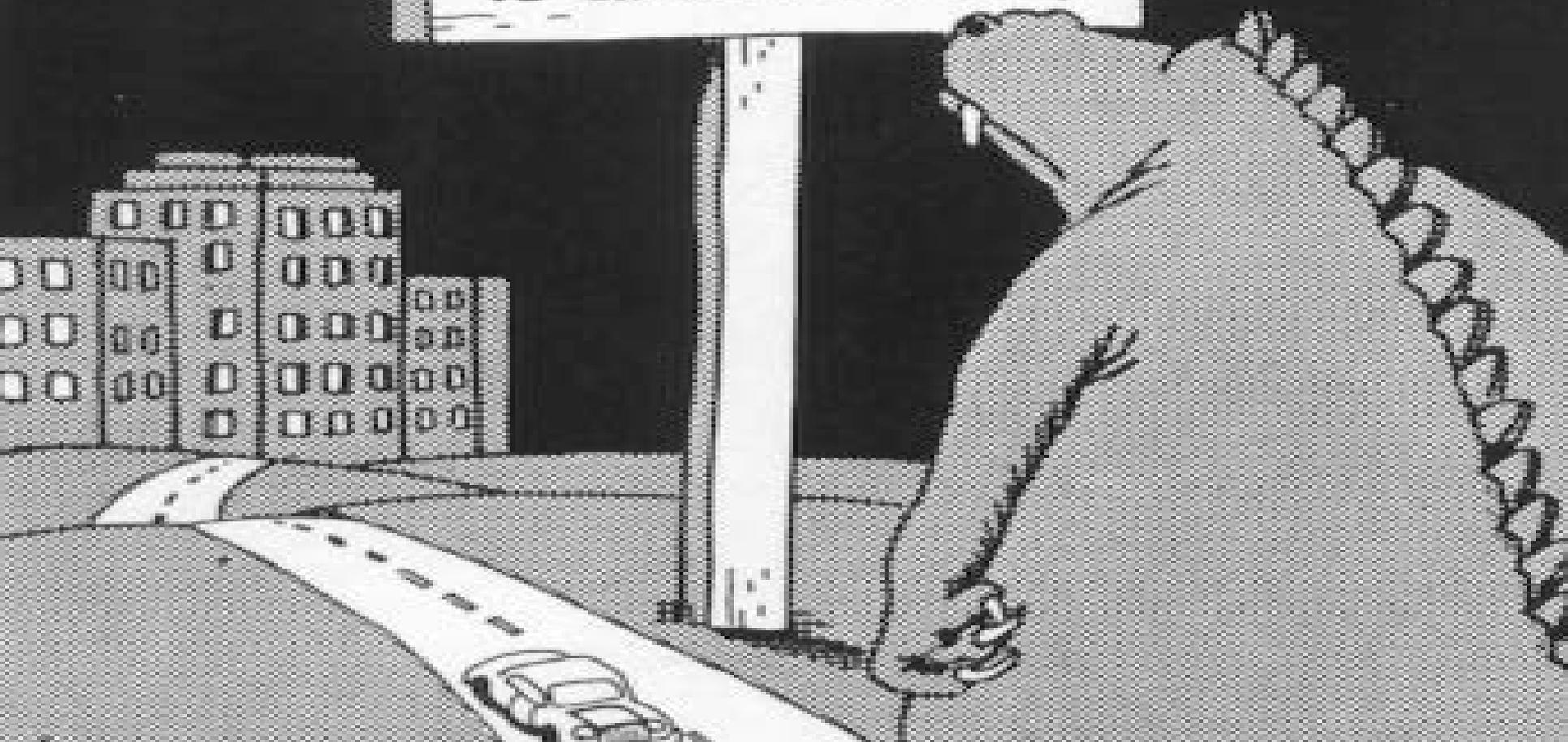
- Generally filed by disgruntled employee, patient, customer or competitor.
- Removes discretion from the government.
- Case filed under seal. Lead time may be 2 to 3 years.

# Qui Tam Risk Management

- Can employees be asked to promise not to file a qui tam suit?

# NOTICE

You must be as  
Tall as this sign  
to attack the city



# Qui Tam Risk Management

- Waivers:
  - Probably not enforceable, definitely a bad PR move.
- Certification of concerns.
- Responding to concerns:
  - Perception is reality.
  - Tension between secrecy & openness.
- What else can you do?? Watch the Compliance Plan webinar.

# FCA Principles

- Historically distinguished between “conditions of payment” and “conditions of participation.”
- Recent Supreme Court case (Escobar) makes the focus on materiality. Would the government have paid the claim had it known? Is the regulatory framework clear?

# 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, take cover immediately.

# 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.

# 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 Dr.

# Stark Quirks

- The offending financial relationship may be unrelated to the referrals. (Lawn mowing)
- “Referral” includes 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.

# Key Concept: Stark Rural Exception

- There is a rural exception protecting **ownership** if you are outside of a Metropolitan Statistical Area (MSA), and 75% of your patients live outside an MSA.
- MSAs are defined by the Census Bureau, and consist of counties.

# Key Concept: Stark Rural Exception

- Note that rural areas can become urban.
- **The rural exception only protects ownership, not other compensation.**
- Deals that would never work in the city may be fine in rural areas.

# Per Click

- If a physician is referring patients to a service, the physician may not be compensated on a “per click/per use” or percentage basis.
  - Example: Physician owns scanner, leases it to hospital for \$500/scan. That is impermissible.

# Per Click

- The same lease is permissible if the payment is a flat fee per month.
- Per click/per use leases are still permissible if the owner does not refer to the lessee.
  - Example: Clinic or hospital leases scanner from a mobile imaging company where the mobile imaging company is not owned by local physicians.

# Stark's Impact on Ancillary Sharing/Joint Ventures

- In rural areas, things are pretty easy.
- In urban areas, joint ventures for DHS are increasingly difficult.
- In an urban area, if a physician leases equipment and techs to a hospital, this is problematic.

# Comp Formula

- Stark limits how physicians can divide revenue.
- It only applies to Medicare and Medicaid revenue.
- Physicians can't get paid for referrals for DHS.

# Stark Landmines

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

# 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 intraorganization 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.

# Typical Relationships

- Medical Director.
- Co-marketing with a physician or device company.
- Grants from drug/device company, possibly research related.
- Leases.

# Relationships with Drug/Device Companies

- Scrutiny on the increase.
- Do you know what is happening in your organization?
- Remember that sales staff have an incentive to characterize things as “ok.”

# Neiman Marcus or Marshall's?

- An off-label use of a device greatly helps cardiac patients.
- The company asks a physician to give a speech about the merits of the device.
- Labeling matters!

# Getting Concrete

- Device rep really wants a physician's advice. Offers to pay \$200/hour if physician will attend a focus group in San Diego.
- Analysis: Stark, Antikickback, 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 San Diego? 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.

# Intermediate Sanctions Analysis

- The device company is a for-profit entity, so there is no issue.

# State Law Analysis

- Antikickback statute.
- State disclosure laws.

# Getting Concrete

- A drug rep offers to pay a physician \$200/hr to listen to their explanation of why their drug is better.

# Getting Concrete Walls

- A drug rep offers to pay a physician \$200/hr to listen to their explanation of why their drug is better.
- Does a physician have a duty to learn about new developments in medical care?

# Food, Fun and Friends

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

# The Therapator

- A device company offers a free treadmill for prescribing their device 10 times each month. Their legal department writes that this is fine because the treadmill is intended to help patients rather than you and is therefore not considered a kickback.

# The “Patient Care” Myth

- Perhaps the best test of whether something may be a kickback is whether it involves cash, a good or service that the practice would otherwise acquire.
- A gift of \$500 is no different than a \$500 piece of equipment, which is no different than a \$500 “fellowship” to pay a nurse.

# A Deal too Good to Pass Up?

- 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.”

# A Deal too Good to Pass Up?

- 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.

# Scholarships

- You want to train an RN on the latest device pump. A seminar in Orlando seems perfect. You ask the device company for a grant to pay for the RN's travel.

# Scholarships

- A trade group obtains 10 scholarships from drug companies to offer them to qualifying practices in rural areas.

# “Incident To” Billing

- Clinic can bill for “incident to” services only if:
  - Clinic pays for the expenses of the ancillary person.
  - Clinic is the sole provider of medical direction.
  - The first visit for the course of treatment is with a physician (later visits may be with the non-physician provider). Note the “new problem” myth.

# “Incident To” Billing

- The service is something typically done in an office.
- **The service is not in a hospital or nursing home. (may be a “shared visit.”)**
- A clinic physician must be in the “office suite.”
- The services should be billed under the supervising physician.

# 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).

# Corporate Practice of Medicine

- State driven.
- Forbids physicians from being controlled by non-professionals.
- Some professional corporation acts prohibit different professions from owning a practice.

# Two Midnight Rule

## § 412.3 Admissions

- (a) For purposes of payment under Medicare Part A, an individual is considered an inpatient of a hospital, including a critical access hospital, **if formally admitted as an inpatient pursuant to an order for inpatient admission by a physician or other qualified practitioner** in accordance with this section and § § 482.24(c), 482.12(c), and 485.638(a)(4)(iii) of this chapter for a critical access hospital. ***This physician order must be present in the medical record and be supported by the physician admission and progress notes***, in order for the hospital to be paid for hospital inpatient services under Medicare Part A. In addition to these physician orders, inpatient rehabilitation facilities also must adhere to the admission requirements specified in § 412.622 of this chapter.

## § 412.3 Admissions cont.

(b) The order must be furnished by a qualified and licensed practitioner who **has admitting privileges** at the hospital as permitted by State law, and who **is knowledgeable about the patient's hospital course**, medical plan of care, and current condition. The **practitioner may not delegate** the decision (order) to another individual who is not authorized by the State to admit patients, or has not been granted admitting privileges applicable to that patient by the hospital's medical staff.

## § 412.3 Admissions cont.

- (b) The physician order also constitutes a required component of physician certification of the medical necessity of hospital inpatient services under subpart B of Part 424 of this chapter.
- (c) The physician order must be furnished at or before the time of the inpatient admission.

## § 412.3 Admissions cont.

(e)(1) Except as specified in paragraph (e)(2) of this section, when a patient enters a hospital for a surgical procedure not specified by Medicare as inpatient only under § 419.22(n) of this chapter, a diagnostic test, or any other treatment, and the physician **expects** to keep the patient in the hospital for only a limited period of time that **does not cross 2 midnights, the services are generally inappropriate for inpatient admission and inpatient payment under Medicare Part A**, regardless of the hour that the patient came to the hospital or whether the patient used a bed.

## § 412.3 Admissions cont.

Surgical procedures, diagnostic tests, and other treatment are generally appropriate for inpatient admission and inpatient hospital payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights. The expectation of the physician should be based on such complex medical factors as patient history and comorbidities, the severity of signs and symptoms, current medical needs, and the risk of an adverse event. The factors that lead to a particular clinical expectation must be documented in the medical record in order to be granted consideration.

## § 412.3 Admissions cont.

- (2) If an unforeseen circumstance, such as a beneficiary's death or transfer, results in a shorter beneficiary stay than the physician's expectation of at least 2 midnights, the patient may be considered to be appropriately treated on an inpatient basis, and hospital inpatient payment may be made under Medicare Part A.

# § 412.46 Medical Review Requirements

(a) Physician acknowledgement.

(1) Basis. Because payment under the prospective payment system is based in part on each patient's principal and secondary diagnoses and major procedures performed, as evidenced by the physician's entries in the patient's medical record, physicians must complete an acknowledgement statement to this effect.

# § 412.46 Medical Review Requirements

- (2) Content of physician acknowledgement statement. [When a claim is submitted, the hospital must have on file](#) a signed and dated acknowledgement from the attending physician that the physician has received the following notice: Notice to Physicians: Medicare payment to hospitals is based in part on each patient's principal and secondary diagnoses and the major procedures performed on the patient, as attested to by the patient's attending physician by virtue of his or her signature in the medical record. Anyone who misrepresents, falsifies, or conceals essential information required for payment of Federal funds, may be subject to fine, imprisonment, or civil penalty under applicable Federal laws.

# § 412.46 Medical Review Requirements cont.

## (3) Completion of Acknowledgement.

The acknowledgement must be completed by the physician at the time that the physician is granted admitting privileges at the hospital, or before or at the time the physician admits his or her first patient. Existing acknowledgements signed by physicians already on staff remain in effect as long as the physician has admitting privileges at the hospital.

# Bottom Line

- Physician expectation controls. Is a two-midnight stay anticipated?  
(possible exception for intense care)
- Government can assert that physician order and supporting documentation are required.

# Timing is Everything

“Our previous guidance also provided for a 24-hour benchmark, instructing physicians that, in general, beneficiaries who need to stay at the hospital less than 24 hours may usually be treated as inpatients. Our proposed 2-midnight benchmark, which we now finalize, simply modifies our previous guidance to specify that the relevant 24 hours are those encompassed by 2 midnights. . .

# Timing is Everything

. . . Contrary to the commenters' suggestion, we do not refer to "level of care" in guidance regarding hospital inpatient admission decisions. Rather, we have consistently provided physicians with the aforementioned time-based admission framework to effectuate appropriate inpatient hospital admission decisions. . .

# Timing is Everything

. . . This is supported by recent findings in the Office of Inspector General (OIG) Hospitals Use of Observation Stays and Short Inpatient Stays for Medicare Beneficiaries, OEI-02-12-0040.”

# Short Stays: Pre 10/1/13 Guidance

## Medicare Benefit Policy Manual

(CMS Pub. 100-02)

### § 10 - Covered Inpatient Hospital Services Covered Under Part A

An **inpatient** is a person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services. **Generally, a patient is considered an inpatient if formally admitted as inpatient with the expectation that he or she will remain at least overnight** and occupy a bed even though it later develops that the patient can be discharged or transferred to another hospital and not actually use a hospital bed overnight.

# Pre 10/1/13 Guidance

The physician or other practitioner responsible for a patient's care at the hospital is also responsible for deciding whether the patient should be admitted as an inpatient. **Physicians should use a 24-hour period as a benchmark, i.e., they should order admission for patients who are expected to need hospital care for 24 hours or more, and treat other patients on an outpatient basis.** However, the decision to admit a patient is a complex medical judgment which can be made only after the physician has considered a number of factors,

# Pre 10/1/13 Guidance

including the patient's medical history and current medical needs, the types of facilities available to inpatients and to outpatients, the hospital's by-laws and admissions policies, and the relative appropriateness of treatment in each setting. Factors to be considered when making the decision to admit include such things as:

- The severity of the signs and symptoms exhibited by the patient; and
- The medical predictability of something adverse happening to the patient.

# Bundled Billing

- DRG. (72-hour rule)
- APC.
- Facility fee.
- New Programs like BCPI, CJR, EPM.

# Professional Services Arrangement



1. Clinic or physicians contract with hospital to provide services.
2. Hospital bills for the services.

# Decision: Provider-Based?

- Pro: Better reimbursement.
- Con: 20% Co-pay.
  - Can't bill "incident to" (shared visit ok).
  - 72-hour rule applies.
- Anything more than 250 yards from the hospital is "off-campus," creating significant regulatory burdens.
- Great webinar from April 2016.

# Sunset provisions

- Section 603
  - Part of the Bipartisan Budget Act of 2015
  - “Treatment of off-campus outpatient departments of a provider”
  - Became law on Nov. 2, 2015
- As of Jan. 1 2017, no payment of facility fees for services in new off-campus departments of providers
  - Does not eliminate provider-based status
  - Doesn’t prevent acquisition of departments
  - 42 CFR 413.65 still in effect (603 amends the statute)
  - Applies only to off-campus departments (not on-campus departments, not remote locations of a hospital)

# Section 603

- Items and services furnished on or after 1/1/2017 in new off-campus outpatient departments of a provider will not be paid under the OPPS
  - Paid instead under other applicable payment system
  - Removes from definition of “covered OPD services” items and services furnished on or after 1/1/2017 by an off-campus outpatient department of a provider
- Determination of “off campus” becomes a bigger deal
  - Discussed in more detail later on CMS determinations in this area

# Provider-Based Requirements

- Public awareness.
- Integrated Clinical services.
  - Privileges at both.
  - Hospital monitors as it would a department.
  - Medical director must report to hospital.
  - Hospital med staff committees/UR oversight.
  - Integrated medical record.
- Financial Integration: shared income and expenses, incorporated in providers cost report and trial balances.
- Additional rules if you are more than 250 yards from the hospital.

# Provider-Based Off Campus

- 100% hospital ownership (i.e. clinic and hospital can't co-own off campus entity).
- Must be under provider control. Personnel decisions, contracts, etc., require hospital approval.
- Administrative reporting must be as frequent as in main provider.
- Billing, HR, records, purchasing, etc., must be integrated and under the main provider's direction.

# Provider-Based Off Campus

- Hospital must employ (not lease) staff “directly involved in delivery of patient care” except those who “would be paid for by Medicare under a fee schedule.”
- Geographic tests (if within 35 miles, ok).

# Compensation

- Many options available:
  - Percentage of billings.
  - RVUs.
  - Hourly.
- Compensation must be reasonable (Stark, tax exemption rules apply).
- Compensation surveys are guidelines, not ceilings.

# QUESTIONS?



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