Health Law 101: Antikickback, Stark and More

Health Law Webinar

October 16, 2024

Fredrikson


Foundations

Our Agenda

- Introduction: Overview of Medicare/Medicaid private insurance.
- Licensing.
- Reimbursement.
- False Claims Act.
- Anti-Kickback/CMP/Fee Split.
- Stark.
- Tax Exemption.

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Our Agenda

- Enrollment.
- Corporate Practice of Medicine.
- Healthcare Pricing.
- HIPAA/Confidentiality/Duty to Warn.
- Tips for doing legal research.

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Preliminary Thoughts

- Who do you believe?
- There are more laws than we can cover here.
  - Never forget state law.
- There are other authorities that aren’t technically laws.
  - Contracts, accreditation, corporate policies. (Choose “”required” carefully!!)

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Conceptualizing the Law

- Laws affecting relationships.
- Laws detailing billing methodology.
- Laws affecting who can do certain things.
- Think of Fruit Loops!

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Conceptualizing the Law

- Can you do that?
- Can you bill for that?

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Conceptualizing the Law

- Can you do that?
- Can you bill for that?
- Can you have that kind of relationship?
- Do you have to ask the patient?
- Can you charge that price?
- Should (must/can?) that be confidential?

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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

Licensing

- Individual
  - Professional licensing.
  - Remember to think about the state!
- Where is a service provided?
  - Physician in Florida has a telehealth encounter with a patient from Georgia.

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Licensing

- Licensing/scope of practice is a state law creature.
- Scope of practice can affect reimbursement. (Medicare, like most payors, requires licensure.)
- Look to state practice act, regulations, licensing board guidance, and licensing board disciplinary action.

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Scope of Practice

- What can a professional do under their state law license?
- Who must supervise?
  - Licensing.
  - Billing.
- Who may delegate?

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Licensing

- Entity.
  - Facility licenses.
  - Corporate Practice of Medicine.
- Example:
  - “We want to open a new pain clinic in New Mexico.”

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Can You Bill For That?

- Medicare.
- Medicaid.
- Third party payers.
- Self-pay.

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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 (ROs).
- Medicare Administrative Contractors (MACs).
- State Agencies (SAs).

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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.
- You can’t charge an out of network MA patient more than Medicare would pay.

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Medicare 101

- Understand if reimbursement is fee for services (FFS), prospective payment (PPS), or something else.
- Benefit categories.
- Conditions of payment.
- Conditions of participation.
- Professional and technical components, facility fees.

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Medicare 101

- Supervision levels. (General, Direct and Personal). See 42 CFR 410.32.
- Who may bill and “incident to” billing.
- Provider-based rules, place of service.
- Graduate medical education, residents, and teaching physicians.

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“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.

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“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.

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Location, Location, Location?

- Does place of service matter?
- Hospital vs. Clinic? Yes, for now.
- Clinic vs. Urgent Care? Probably not.
- In a facility, the total payment is higher, but the professional fee is lower.

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Teacher, Teacher

- Medicare pays hospitals to train residents.
- There is both direct and indirect “Graduate Medical Education.”
- The teaching physician gets paid for their own work, not the work of the resident. See 42 CFR 410.172.

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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.

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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.
    - DMEPOS.
    - ASC.
    - Clinic.

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Conditions of Participation

- Like licensing rules for government health care programs.
  - Medicare.
  - Medicaid.
- Accreditation largely subsumes.
- Example:
  - Opening a new ASC, HHA, but not a clinic or IDTF.

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Conditions of Participation (CoP)

- CoPs determine whether a facility may remain enrolled in Medicare.
- Many CoPs are highly technical, reflecting things such as signature requirements.
- Conditions of Participation are not automatically Conditions of Payment.
- There has been an evolution, culminating in the Supreme Court case *Universal Health Services v. Escobar.*

What Are Words For?

- Why have Conditions of Payment if everything is one?
- Why separate “Conditions of Payment” and “Conditions of Participation” if they are synonymous?
- Don’t refund when Conditions of Participation are violated!

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Violating CoPs Doesn't Cause An Overpayment

- MAC, CERT and Recovery Auditor staff shall not expend Medicare Integrity Program (MIP)/MR resources analyzing provider compliance with Medicare rules that do not affect Medicare Payment. Examples of such rules include violations of conditions of participation (COPs), or coverage or coding errors that do not change the Medicare payment amount.
  - Program Integrity Manual, Ch. 3,§3.1 - Introduction

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United States ex rel. Hobbs v. Medquest Assocs., Inc., 711 F.3d 707 (6th Cir. 2013)

- MedQuest's actions at the Nashville-area centers clearly were at odds with the goals and aims of the Medicare program in several respects, and the Government has raised reasonable arguments in support of its claims. We have little sympathy for MedQuest, which sometimes skirted and appears to have often ignored applicable regulations in the conduct of its centers. However, because these regulations are not conditions of payment, they do not mandate the extraordinary remedies of the FCA and are instead addressable by the administrative sanctions available, including suspension and expulsion from the Medicare program.

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.

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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!

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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
- Organizations can have radically different CCRs. A lower CCR means a higher “mark-up.”

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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.)

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Key Players

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

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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!

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Reporting: Overpayments & More

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

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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.

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False Claims Act

- Civil War statute, updated in the 1980s.
- Federal law allowing penalties of treble damages plus $5,500 - $11,000 per claim. Rules increase the penalty to $12,537 to $25,076.
- 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?

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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.

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Qui Tam

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

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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 and openness.
- What else can you do?? Compliance plans.

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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?

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FCA Materiality

- “The materiality standard is demanding. The False Claims Act is not "an all-purpose antifraud statute," or a vehicle for punishing garden-variety breaches of contract or regulatory violations. A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment. Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance. Materiality, in addition, cannot be found where non-compliance is minor or insubstantial.”

Escobar, 136 S. Ct. at 2003 (citations omitted)

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Escobar, 136 S. Ct. at 2004.

- "Likewise, if the Government required contractors to aver their compliance with the entire U. S. Code and Code of Federal Regulations, then under this view, failing to mention noncompliance with any of those requirements would always be material. The False Claims Act does not adopt such an extraordinarily expansive view of liability."

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Can You Have That Kind of Relationship?

- Anti-kickback/CMP.
- Physician Self-referral. (“Stark.”)
- Eliminating Kickbacks in Recovery Act. (“EKRA.”)
- Fee splitting.
- Sunshine. (Just reporting.)
- Antitrust.

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Anti-kickback Statute

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

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Anti-kickback Statute

- Intent is everything. The question: Is the payment intended to induce a favor?
- If the payment is “bait” to get someone to listen, that is defensible. If the gift is to prompt action in the form of referrals, that is probably a felony.
- “Why” is always the operative question.

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Antikickback Protection

- Safe harbors exist, but they aren’t THAT important.
- They will cover many payments for services as long as the payment is reasonable for the work done, contract is written, etc.
- Common sense takes you a long way with the antikickback law. Remember, you don’t need to fit in a safe harbor.
- Beware of bad advice: “There is no favorable Advisory Opinion, suggesting this is illegal.”

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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 a person “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!
- Gov. says anti-kickback exceptions protect under CMP, but not vice-versa. (Does that make sense??)

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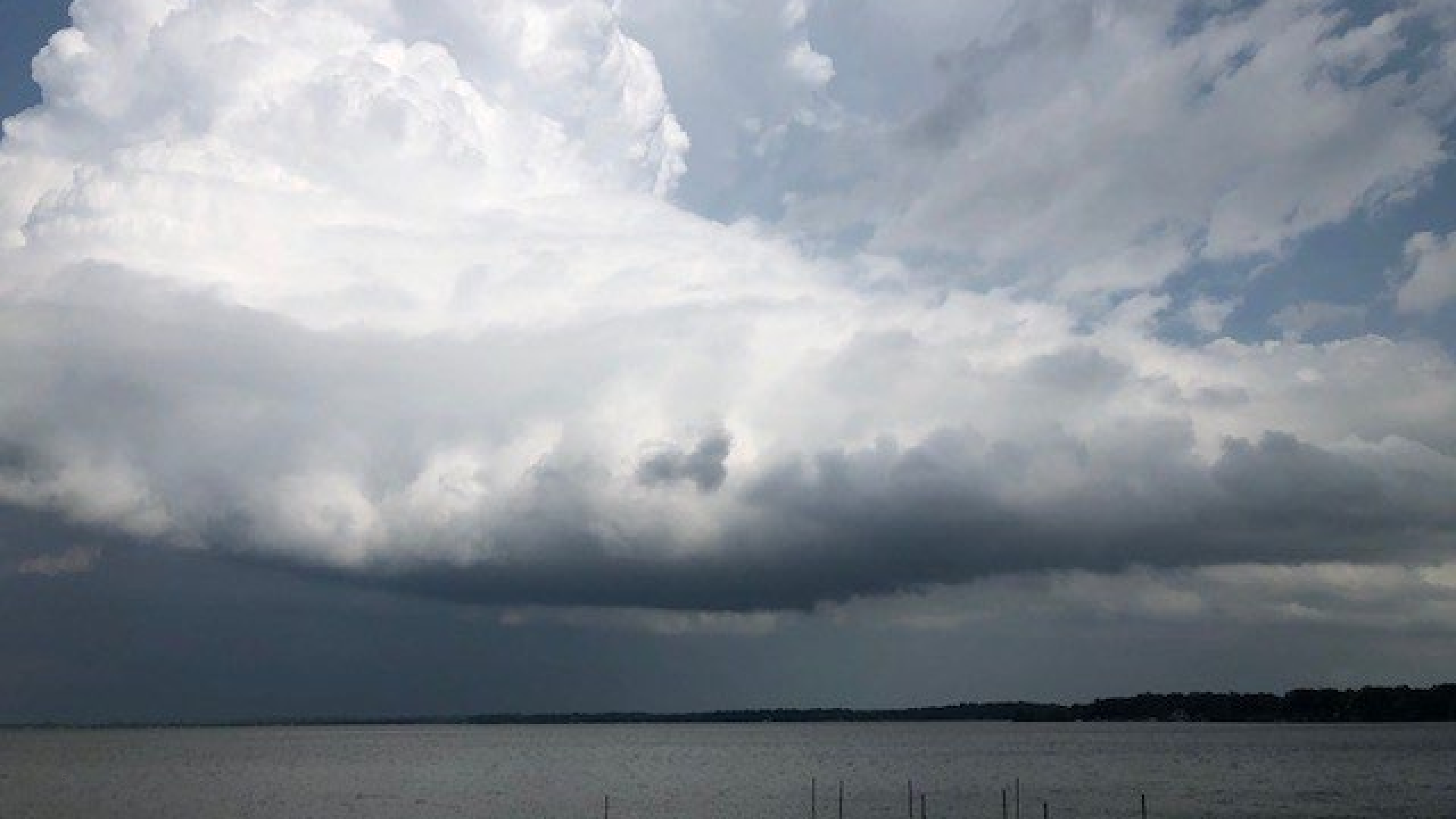


STARKS
Bar & Grill
3125
Dodd Rd.
BAR HOURS
KITCHEN HOURS
NO PARKING

Stark Issue Spotting

- Does a physician create a plan of care including a designated health service?
- If so, is there a financial relationship with the physician or their family member (defined broadly!)
- If so, you need to meet an exception to Stark.

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Stark Issue Spotting

- The word “referral” is misleading!! It is all about the plan of care!
- The financial relationship can be totally unrelated to the plan of care. If a physician’s family member does snow removal for a hospital, Stark is implicated.
- All hospital services are DHS.

“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.

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.

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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.

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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.

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“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.”

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EKRA

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

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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.

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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.

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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?

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).

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Corporate Practice of Medicine

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

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"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.
- Divvying up a market: non-circumvention clauses?

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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.

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When Antitrust Matters

- Negotiations with insurers.
- Relationships with hospitals.
- Peer review.
- Joint ventures.
- Pricing.
- Mergers.

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Can you Charge That Price?

- Pricing.
- Beneficiary inducement.

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“Let’s Make A Deal” or “The Price Is Right?”

- There are two ways to buy a good or service:
    - Explicit agreement on terms.
    - Implied contract.
- Implied contracts are rare in any other industry.
- If parties disagree about a term in an implied contract, a court will impose a “reasonable” result.
- Name another situation where people pay a percentage of billed charges….

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Peril of the Percentage

- Your “standard charge” for a service is $5,000. A patient without insurance is eligible to pay 70% as payment in full. What is your charge for the service? (Show your work!)

  A. *$5,000.*

  B. *$3,500.*

  C. *What the “average patient” pays?*

  D. *We need more information.*

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Can I Have Different Prices For Different Patients?

- Absolutely. Every organization has multiple charges for identical services.
- Beware of catchy phrases like “you can’t discriminate.”
- Inconsistent pricing for services isn’t inherently “illegal,” but there are collateral consequences, including claims of fraud.

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I Have To Give Medicare My Lowest Price, Right?

- Wrong. Medicare pays the lower of:
  - *Actual charge.*
  - *Fee schedule amount.*
  - *Usual and customary charge.*
- Usual and customary charge is defined as your median (50th percentile) charge. Medicare Claims Processing Manual, Ch. 23, §80.3.1.

42 CFR § 405.503(b)

- This regulation defines “customary charges” as “the uniform amount which the individual physician or other person charges in the majority of cases for a specific medical procedure or service.”

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Actual Charges May Vary

- If the individual physician or other person varies his charges for a specific medical procedure or service, so that no one amount is charged in the majority of cases, it will be necessary for the carrier to exercise judgment in the establishment of a “customary charge” for such physician or other person. In making this judgment, an important guide, to be utilized when a sufficient volume of data on the physician's or other person's charges is available, would be the median or midpoint of his charges, excluding token and substandard charges as well as exceptional charges on the high side. A significant clustering of charges in the vicinity of the median amount might indicate that a point of such clustering should be taken as the physician's or other person's “customary” charge. Use of relative value scales will help in arriving at a decision in such instances.

42 CFR § 405.503(b)

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I Have To Give Medicaid My Lowest Price, Right?

- Maybe. Depends on state law.
- In some states the “usual and customary” charge is defined as the charge that you charge most often. (Mode).
- Some states follow Medicare. (Median).
- Some states require Medicaid to be the lowest. (Minimum).

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Price Transparency and No Surprises Act

- People often conflate them. They are different.
- Price Transparency only applies to hospitals, requiring disclosure of ALL contracted rates, and listing shoppable services.
- No Surprises Act has multiple facets:
  - Emergency services, and physician services when a patient is at an in-network hospital/ASC.
  - Currently, when a patient isn’t using their insurance to pay for a service, though this may expand.

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Research Tips: 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).

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Research Tips

- Proposed Rule vs. Final Rule.
- Never forget state law. Some are mighty hard to find!! (Is local counsel an advantage???)

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SSSSSources of Authority??

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

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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.

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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).

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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 Can’t 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.

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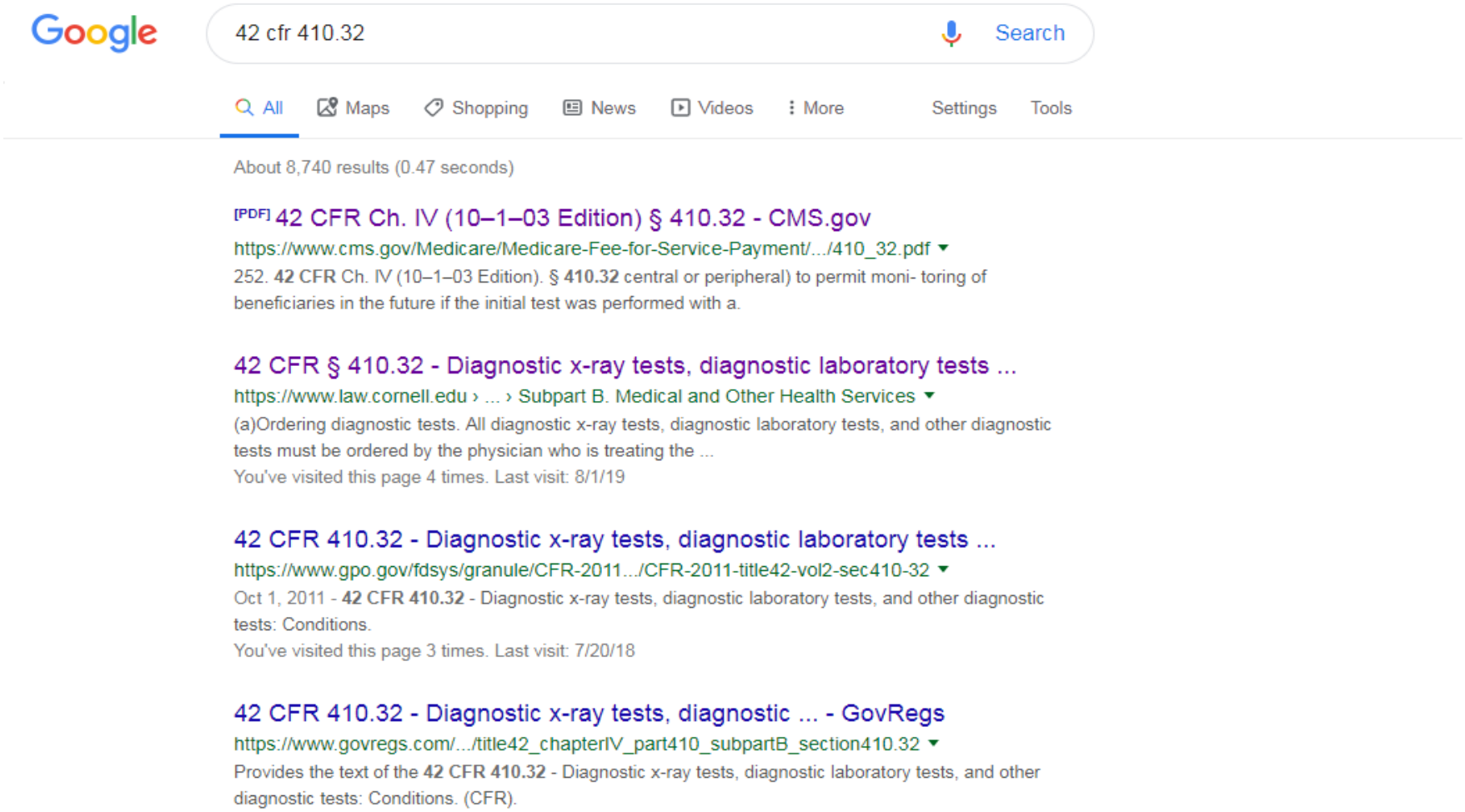
Google with Caution!



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[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.

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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

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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/.

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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)

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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

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Is the Manual Up-to-Date?

Medicare Claims Processing Manual

Chapter 3 - Inpatient Hospital Billing

Table of Contents

(Rev. 4337, 07-18-19)

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National vs. Local Coverage Determinations

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

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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

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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)

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LCDs

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

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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).

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HIPAA

- Make sure you get two “A”s in the class!
- Outgrowth of antidepressant samples sent unsolicited to folks.
- Protects confidentiality, but is broad, counter-intuitive.
- It protects many things one might not expect.

HIPAA

- If someone is in the waiting room, is that protected?
- Key terms:
  - Protected Health Information. (PHI.)
  - Covered Entity. (CE.)
  - Minimum Necessary.
  - Business Associate/Agreement. (BAA.)

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What Is PHI?

- Individually identifiable information that is held or transmitted by a CE* or BA* in any form or media.
  - Past, present, or future physical or mental health,
  - Provision of health care to the individual, or
  - Past, present, or future payment for the provision of health care to individual.

* Covered Entity and Business Associate

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Permitted Uses And Disclosures

- No authorization (or consent) required:
  - Disclosure to the individual. (and/or personal representative.)
  - Treatment, payment, and health care operations.

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Treatment

- Provision, coordination, or management of health care and related services by CE.
- Includes consultation between CE and other health care providers relating to a patient.
- Includes referrals.

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Payment

- Any activities to obtain payment or be reimbursed for health care services.
- Examples:
  - Billing and collection activities.
  - Reviewing services for medical necessity, coverage, and justification of charges.
  - Utilization review activities.

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Heath Care Operations

- Financial, administrative, legal, and quality improvement activities used to run Regina's business and support treatment and payment functions.
  - E.g., conducting or arranging for medical review, legal, and auditing services.

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Other Permitted Disclosures

- Disclosure to Family/Friends.
- Public Health Activities.
  - To public health authority.
  - To report child abuse/neglect.
  - To FDA.
- Law Enforcement Purposes.
- Abuse, Neglect, and Domestic Violence.
- Research.
  - Limited if no patient authorization. (e.g., PHI of decedents; data use agreements.)
- Workers' Compensation.
- Judicial and Administrative Proceedings.

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“Business Associate” is a person/entity who:

- Performs a function or activity involving the use or disclosure of PHI “on behalf of ” CE.
- Doesn’t include members of CE’s workforce.
- May be another covered entity.
- Provides legal, actuarial, accounting, consulting, management, administrative, or financial services, where provision of such service involves disclosure of PHI.
- Must have a BAA.

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De-identification – Safe Harbor

- Name
- Geographic subdivisions – including zip code
- Elements of dates (except year)
- Telephone number
- Fax number
- E-mail
- SSN
- Medical record number
- Any other unique identifying characteristic or code
- Health plan beneficiary number
- Account number
- Certificate or license number
- License plate number
- Device identifiers
- URLs
- IP address
- Biometric identifiers including fingerprints and voice prints
- Full face photographic images

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Breaches

- May require notification to the patient.
- May require notification to the Office of Civil Rights.
- May require notice to the media.

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