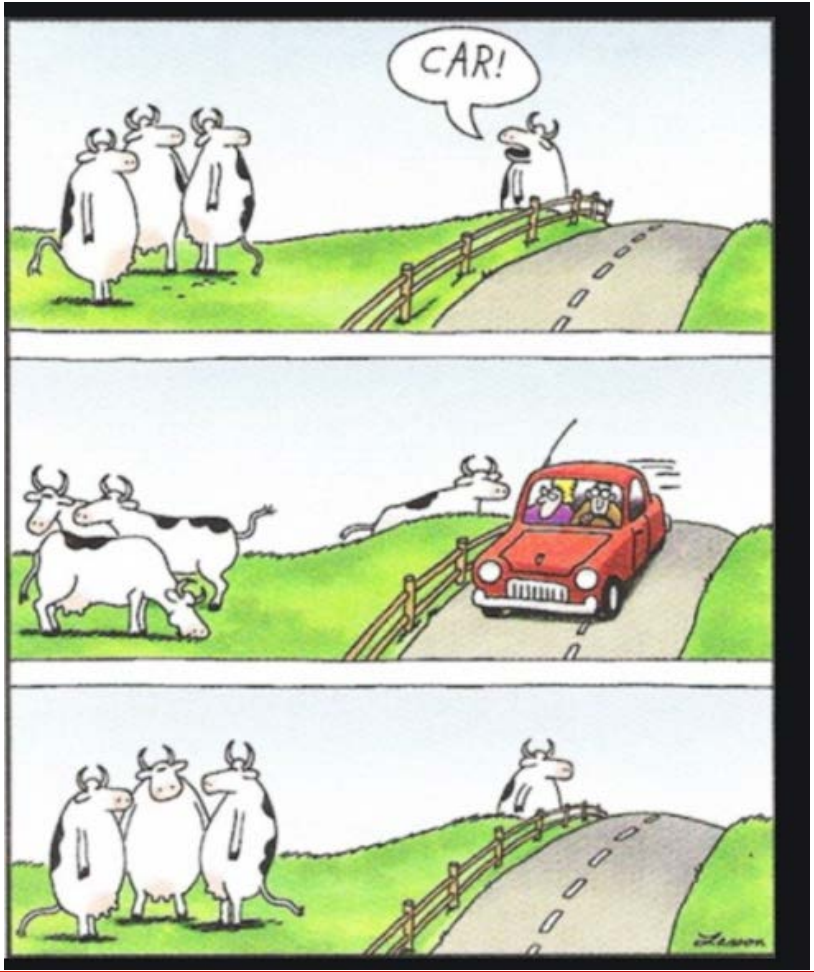
But I Heard That's Illegal

October 14, 2020

Fredrikson & BYRON, P.A.

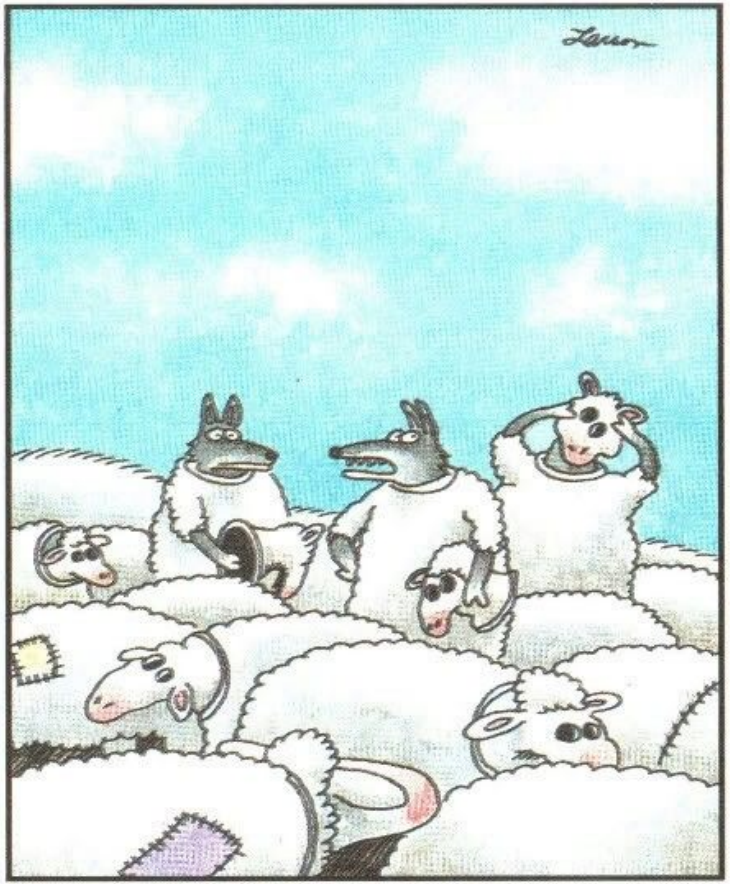

CAR!

The Problem

- An employee presents with a compliance concern. “But I heard that’s illegal.”
- You need to evaluate the concern and, if appropriate, dissuade them.
- Law and psychology merge.

There's a Billy Joel Song for That!

- Assessing the individual's credibility.
  - Listen with an open mind.
  - Do you have an employee who cries wolf?



"Wait a minute! Isn't anyone here a real sheep?"

There's a Billy Joel Song for That!

- Assessing the individual's credibility.
  - Listen with an open mind.
  - Do you have an employee who cries wolf?
  - The stopped clock axiom.

Choose Wisely

- You can only persuade the persuadable.
- Power of coffee.
- How much thought have you given to your interviewing process?
- “Name that whistleblower.”

Aha!

- Is it better to take things under advisement?
- Be sure to ask for citations to authority.

Regulatory Hierarchy

- Constitution (due process, contracts clause, enumerated powers).
- Statutes (U.S. Code/Social Security Act.)
- Regulations/National Coverage Determinations.
  - Code of Federal Regulations.
  - State Regulations or Administrative Code.
  - NCD Manual. (A binding manual!).

Regulatory Hierarchy

- Everything else is nonbinding.
  - Manuals.
  - Local coverage determinations.
  - Guidance from contractors.
  - Regulatory Preambles.
  - FAQs.

SSA 1871(a)(2) is Our Friend

"No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this title shall take effect unless it is promulgated by the Secretary by regulation under paragraph (1)."

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.

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

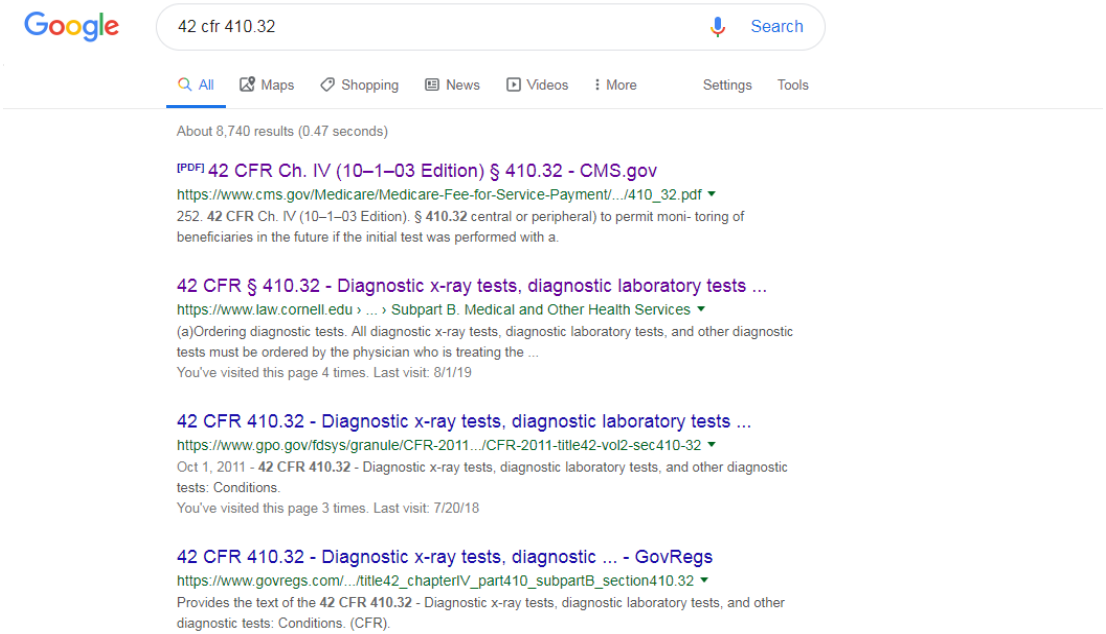
On November 16, 2017, the Attorney General issued a memorandum ("Guidance Policy") prohibiting Department components from issuing guidance documents that effectively bind the public without undergoing the notice-and-comment rulemaking process. Under the Guidance Policy, the Department may not issue guidance 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.

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 C.F.R. 405.1062(a).
- "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).

Google With Caution!



The Power of the Internet?

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 ther-

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

What's This Gibberish??

(iii) *Medical necessity.* The entity submitting the claim may request additional diagnostic and other medical information from the ordering physician or nonphysician practitioner to document that the services it bills are reasonable and necessary. If the entity requests additional documentation, it must request material relevant to the medical necessity of the specific test(s), taking into consideration current rules and regulations on patient confidentiality.

(4) *Automatic denial and manual review.* (i) *General rule.* Except as provided in paragraph (d)(4)(ii) of this section, CMS does not deny a claim for services that exceed utilization parameters without reviewing all relevant documentation that is submitted with the claim (for example, justifications prepared by providers, primary and secondary diagnoses, and copies of medical records).

(ii) *Exceptions.* CMS may automatically deny a claim without manual review if a national coverage decision or LMRP specifies the circumstances under which the service is denied, or the service is specifically excluded from Medicare coverage by law.

(e) *Diagnostic laboratory tests furnished in hospitals and CAHs.* The provisions of paragraphs (a) and (d)(2) through (d)(4) of this section, inclusive, of this section apply to all diagnostic laboratory test furnished by hospitals and CAHs to outpatients.

[62 FR 59098, Oct. 31, 1997, as amended at 63 FR 26308, May 12, 1998; 63 FR 53307, Oct. 5, 1998; 63 FR 58906, Nov. 2, 1998; 64 FR 59440, Nov. 2, 1999; 66 FR 58809, Nov. 23, 2001; 69 FR 66421, Nov. 15, 2004; 72 FR 66398, Nov. 27, 2007; 75 FR 73615, Nov. 29, 2010; 77 FR 69361, Nov. 16, 2012; 83 FR 60073, Nov. 23, 2018; 85 FR 19286, Apr. 6, 2020; 85 FR 27620, May 8, 2020; 85 FR 54871, Sept. 2, 2020]

§ 410.33 - Independent diagnostic testing facility.

Electronic Code of Federal Regulations

We invite you to try out our new beta eCFR site at https://ecfr.federalregister.gov. We have made big changes to make the eCFR easier to use. Be sure to leave feedback using the Help button on the bottom right of each page!

e-CFR data is current as of October 7, 2020

Title 42: Public Health
PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS
Subpart B—Medical and Other Health Services

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§410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

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)

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

What is “Illegal” Anyway?

- Distinguish between criminal, civil and administrative provisions.
- Federal, state or local.

Examples

Poorly Privileged Physician Parable

- A physician did a surgical procedure for which she wasn't credentialed.
- Where do we look?
  - Accreditation?
  - Conditions of Participation?
  - Conditions of Payment?

42 CFR 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. In addition, inpatient rehabilitation facilities also must adhere to the admission requirements specified in § 412.622.

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.

CMS: We Want the System to Be Fair.

"It has come to our attention that some otherwise medically necessary inpatient admissions are being denied payment due to technical discrepancies with the documentation of inpatient admission orders" such as "missing practitioner admission signatures, missing co-signatures or authentication signatures, and signatures occurring after discharge…

CMS: We Want the System to Be Fair.

….We have concluded that if the hospital is operating in accordance with the hospital CoPs, medical reviews should primarily focus on whether the inpatient admission was medically reasonable and necessary rather than occasional inadvertent signature documentation issues unrelated to the medical necessity of the inpatient stay…

CMS: We Want the System to Be Fair.

…Therefore, we are proposing to revise the regulations at 42 CFR 412.3(a) to remove the language stating that a 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."

- 83 Fed. Reg. 20448

“Under Coding is Fraud!”

- Oft-repeated but let’s think about it?
- Consider the issue in other contexts.
- What do the “experts” say?

“Undercoding is Fraud!” – the AAPC?

“In general, fraud is defined as making false statements or representation of material facts to obtain some benefit or payment for which no entitlement would otherwise exist. These acts may be committed either for the person’s own benefit or for the benefit of some other party. In other words, fraud includes the obtaining of something of value through misrepresentation or concealment of material facts.” (Attributed to a Medicare Learning Network document)

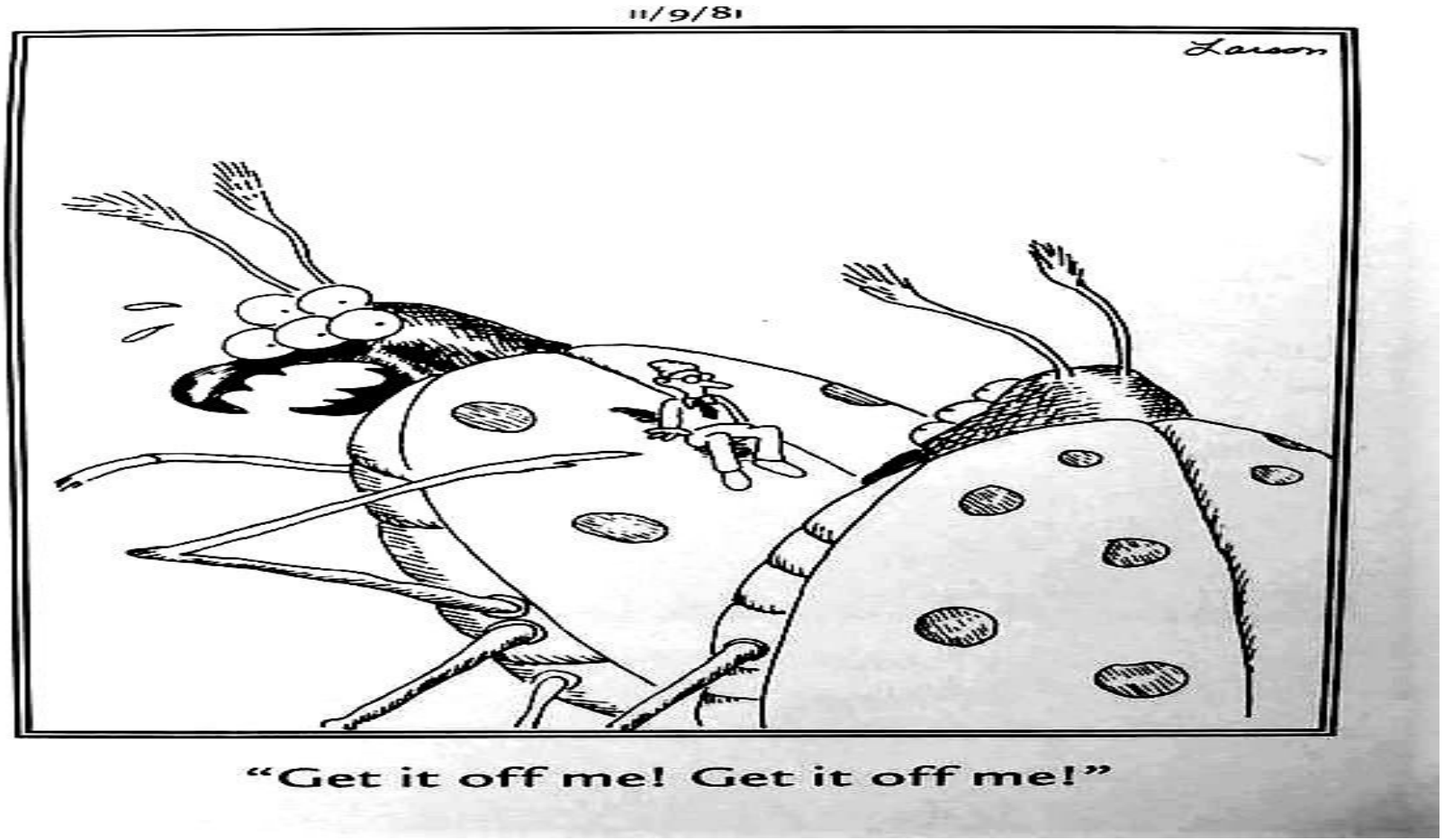
“Undercoding is Fraud” – the AAPC?

“Deliberate under coding is, in reality, “making a false statement” about the services provided, and is ultimately a “misrepresentation” of the facts. The fact sheet gives an example of fraud as “knowingly billing for services that were not furnished,” which would apply if services are purposely under coded.”

- *AAPC Knowledge Center April 4, 2004 Article

“Coders Need Insurance/Risk Jail!”

- Insidious.
- Hard to disprove, but empirical evidence is strong.
- Understand how indemnification works.
- Consider an indemnification policy.



That Employee Certification...

Suspicious Specialty Society

- AANS: To qualify for “partial” removal, at least 1/3 of the body must be removed.
- In conferences, they suggest that billing when less than 1/3 is removed is fraud.
- The doctor bills for a removal if 20% of the vertebrae is removed.

What is the Authority?

- Who decides coding principles?
- Does the payor matter?
- How much deference is the specialty society entitled to?

What is a Corpectomy?

- Code 63081: Vertebral corpectomy (vertebral body resection), partial or complete, anterior approach with decompression of spinal cord and/or nerve root(s); cervical, single segment.

Unreviewed Ultrasounds

- Allegations that an OB was allowing techs to review the ultrasound.
- Tech dictated a report. The physician was signing them, but generally the text of the report was unedited. Compliance was confident that the physician was only looking at some of the scans.
- Patients were waiting a few days to get the report from the physician.

Consider the Code

- Ultrasound, pregnant uterus, real time with image documentation, fetal and maternal evaluation, first trimester(< 14 weeks 0 days), transabdominal approach; single or first gestation.

Relevant Rules?

- Medicare.
- Medicaid.
- Private payors.
- Licensure/scope of practice?

Context Clues

- A physician has incredible RVUs.
- There are allegations that he isn't seeing all of the patients.
- Patients are known to wait 3 hours for an appointment, clinics often run until 7 pm, driving staff crazy.

Angsty Alliterative Auditor

- E&M reviews find missing documentation.
- The reviewer believes a refund is necessary.
- They threaten to call the OIG.

Case of the Crazed Counselor

- Former prosecutor writes a letter explaining that crediting a physician for reading Holter monitor data violates Stark.
- The letter opens “you are committing fraud…”

The LCD

- LCD bars physician with any financial relationship with a device company from ordering their device.
- Company wants to _____.

The LCD

- LCD bars physician with any financial relationship with a device company from ordering their device.
- Company wants to _____.
  - A) Comply.
  - B) Defer.

What Are Words For?

- Internal reviews, “audits,” and self-examinations can bite.
- “The review found an overpayment of $11,436.”
- “This service cannot be billed with code x.”

Capsule Compensation Conundrum

- GI group credits physicians for GI track capsule endoscopy.
- They hear it is a DHS under Stark.
- Their lawyer says “no, it isn’t a DHS.”
- They tell the lawyer he is wrong.

Capsule Compensation Conundrum

- List of DHS says!

78813	PET image full body
78814	PET image w/ct lmtd
78815	PET image w/ct skull-thigh
78816	PET image w/ct full body
78999	Nuclear diagnostic exam
91110	Gi tract capsule endoscopy
91111	Esophageal capsule endoscopy
92132	Cpmtr ophth dx img ant segmt
92133	Cmptr ophth img optic nerve
92134	Cptr ophth dx img post segmt
92227	Remote dx retinal imaging
92228	Remote retinal imaging mgmt

Capsule Compensation Conundrum: Statute Says…

(A) Clinical laboratory services.

(B) Physical therapy services.

(C) Occupational therapy services.

(D) Radiology services, including magnetic resonance imaging, computerized axial tomography, and ultrasound services.

(E) Radiation therapy services and supplies.

(F) Durable medical equipment and supplies.

(G) Parenteral and enteral nutrients, equipment, and supplies.

(H) Prosthetics, orthotics, and prosthetic devices and supplies.

(I) Home health services.

(J) Outpatient prescription drugs.

(K) Inpatient and outpatient hospital services.

(L) Outpatient speech-language pathology services.

SSA § 1877(h)(6)

How Do You Know When You're Done?

Sneaky Sleep Study Regulation

- (f) *Payment prohibition.* No Medicare payment will be made to the supplier of a CPAP device if that supplier, or its affiliate, is directly or indirectly the provider of the sleep test used to diagnose the beneficiary with obstructive sleep apnea. This prohibition does not apply if the sleep test is an attended facility-based polysomnogram.
    - 42 CFR § 424.57

Take Me Home

- Read carefully.
- Determine validity:
  - Is it in a binding document?
  - Check the dates.
  - Climb the ladder.

Presenter

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