Refunding Wisely: Avoiding Doing the Right Thing the Wrong Way

Health Law Webinar

April 12, 2023

Fredrikson

Where Law and Business Meet®

Agenda

- Caption Contest
- Conducting a Factual and Legal Analysis
- Refund Logistics:
  - *How far back do you go?*
  - *Who do you send it to?*
  - *What do you say?*
  - *When do you need to refund?*

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Caption Contest Winners from March

- **1st Place:** What...?? Isn't there such thing as nighttime bird watching?
  - *Elise Reynolds*
- 2nd Place: Oh, uhm...Hi. You're up early.
  - *Kelly Cooper*
- 3rd Place: No cause for alarm; I'm just checking to see if you're wearing your mask. Did you hear that masks are no longer required? LOL, I'm screwed.
  - *Kay Larsen*

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The Duty to Refund

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The Old Days: SSA 1128B. [42 U.S.C. 1320a–7b]

- Whoever has knowledge of…any event affecting his initial or continued right to any [benefit or payment under any federal health care program]…and conceals or fails to disclose such event with an intent to fraudulently secure [the] benefit or payment…shall be guilty of a felony, and upon conviction thereof fined not more than $25,000 or imprisoned for not more than five years or both.”

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The 60 Day Provision: 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.*

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The 60 Day Provision: 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.*

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What is “identified?” 42 CFR §401.305(a)(2)

- “A person has identified an overpayment when the person has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment. A person should have determined that the person received an overpayment and quantified the amount of the overpayment if the person fails to exercise reasonable diligence and the person in fact received an overpayment.”

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Is That About to Change?

- A proposed rule would dramatically modify the definition.
- The proposal deletes all references to “quantification.”
- Many a proposed rule has died on the vine.

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The Proposal: 87 F.R. 79452

- (2) A person has identified an overpayment when the person knowingly receives or retains an overpayment. The term “knowingly” has the meaning set forth in 31 U.S.C. 3729(b)(1)(A).

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What is “identified?” 42 CFR §401.305(a)(2)

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The Big Picture Today (For Medicare, and Sort Of Medicaid)

- The 60-day clock runs only when the overpayment is "identified."
- The duty to "report and return" applies to an overpayment.
- The statute applies to both Title XVIII and XIX. The regulation is Medicare only!

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What About Private Payors?

- Contract.
- State law.
- HIPAA.
- Don’t buy the “you must rebill, but bummer about the timely filing” gambit.

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What is an Overpayment?

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SSA §1128J(d)(4)

- Overpayment.—The term “overpayment” means any funds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such title.*
- *This is important!!!

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42 CFR §401.303

- "*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.*"

- *This is still important!!!

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Applicable Reconciliation: Can You Offset Underpayments?

- "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.*
  - *Offsetting underpayments seems entirely consistent with the statute, and CMS's interpretation seems baseless.*
  - *A theme: don't voluntarily unreasonably penalize yourself.*

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The Overpayment Checklist

- What is the “rule?” Have we violated it?
- Is the “rule” valid?
- Was the rule in effect during the period in question?
- What legal limitations may eliminate liability?
  - *For Medicare, are we “without fault?”*
  - *For private payors, is there a state law helps?*
  - *What is the statute of limitations/time limit on recovery?*

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Reading Rules

- The differences between may/must, can/shall.
- Dig into the details. Incident to: the difference between “new problem” and “course of treatment.”
- Is what you are looking at binding? If it is a contractor policy, is it YOUR contractor? If it is a contractor policy, however, there is a bigger issue!
- Mind the gap? Check that effective date!!

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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!).*

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Regulatory Hierarchy (Lowerarchy?)

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

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SSA 1871(a)(2): Gotta Be A Rule

- "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)."

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The Government Disavows Manuals

- “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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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.

The Brand Memo is Gone…Or is it?

- In July 2021 Attorney General Merrick Garland revoked the "Brand Memo."
- What is the legal significance of the memo?
- What is the state of the law?

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Azar v. Allina, 139 S.Ct. 1804, 1809 (2019)

- “Notably, Congress didn’t just adopt the APA’s notice-and-comment regime for the Medicare program. That, of course, it could have easily accomplished in just a few words. Instead, Congress chose to write a new, Medicare-specific statute. The new statute required the government to provide public notice and a 60-day comment period (twice the APA minimum of 30 days) for any “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 [Medicare].” 42 U.S.C. § 1395hh(a)(2).”

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The ICD Investigation

- An NCD includes this:

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 three (3) months; or,
    - Had an MI within the past 40 days; or,
    - Clinical symptoms and findings that would make them a candidate for coronary revascularization.

   For these patients identified in B2, a formal shared decision making encounter must occur between the patient and a physician

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The ICD Investigation

For each of the six (6) covered indications above, the following additional criteria must also be met:

1. Patients must be clinically stable (e.g., not in shock, from any etiology);
2. LVEF must be measured by echocardiography, radionuclide (nuclear medicine) imaging, cardiac Magnetic Resonance Imaging (MRI), or catheter angiography;
3. Patients must not have:
    - Significant, irreversible brain damage; or,
    - Any disease, other than cardiac disease (e.g., cancer, renal failure, liver failure) associated with a likelihood of survival less than one (1) year; or,
    - Supraventricular tachycardia such as atrial fibrillation with a poorly controlled ventricular rate.

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The ICD Investigation

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) trials (42 CFR 405.201).

(This NCD last reviewed February 2018.)

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NCDs Do NOT Automatically Limit Coverage

- 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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Note the Heading On NCDs

A. General

B. Nationally Covered Indications

C. Nationally Non-Covered Indications

D. Other

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210.2.1 – Screening for Cervical Cancer with Human Papillomavirus (HPV) Testing (Effective July 9, 2015)

- **B. Nationally Covered Indications**

  Effective for services performed on or after July 9, 2015, CMS has determined that the evidence is sufficient to add Human Papillomavirus (HPV) testing once every five years as an additional preventive service benefit under the Medicare program for asymptomatic beneficiaries aged 3265 years in conjunction with the pap smear test. CMS will cover screening for cervical cancer with the appropriate US Food and Drug Administration approved / cleared laboratory tests, used consistent with FDA-approved labeling and in compliance with the Clinical Laboratory Improvement act CLIA regulations.

- **C. Nationally non-covered Indications**

  Unless specifically covered in this and CD, any other end CD, by Statute or regulation, preventive services are non-covered by Medicare.

- **D. Other**

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240.2.1 – Home Use of Oxygen in Approved Clinical Trials (Effective March 20, 2006)

- **B. Nationally Covered Indications**

  Effective for services performed on or after March 20, 2006 the home use of oxygen is covered for those beneficiaries with arterial oxygen partial pressure measurements from 56 to 65 mmHg or oxygen saturation at or above 89% or are enrolled subjects in clinical trials approved by the Centers for Medicare & Medicaid services and sponsored by the National Heart, Lung & Blood Institute (NHLBI).

- **C. Nationally non-covered Indications**

  N/A

- **D. Other**

  This policy does not alter Medicare coverage for items and service that may be covered or non-covered according to the existing national coverage determination for the home use of oxygen provided outside the context of approved clinical trials (National Coverage Determination Manual, section 240.2 and 310.1.

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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 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).*

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If You Do Refund, to Whom?

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

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Poll: How Far Back Must You Go?

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

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How Far Back Must You Go?

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

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Social Security Act §1870

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

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Social Security Act §1870

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

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

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How Does §1870 Work?

- Focus only on the YEAR payment is made.
- Payment made 1/4/17. Can recover 5 years after 2017, so count: 2018, 19, 20, 21, 22. Recovery possible through 12/31/22.
- Payment made 12/31/16. If new provision applies, 2017, 18, 19, 20, 21. Recovery until 12/31/21.
- Note that references to “five years” are very misleading. In life, simplicity too often trumps accuracy.

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Social Security Act §1879

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

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Social Security Act §1879

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

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Social Security Act §1879

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

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The Government Wants Refunders To Ignore §1879

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

– 81 FR 7666

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42 C.F.R. §405.980

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

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

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

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

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42 C.F.R. §405.902

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

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How Far Back Must You Go?

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

– 42 CFR 401.305(f)

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CMS Thinks You Must Do More Than Contractors

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

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CMS Thinks You Must Do More Than Contractors

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

– 81 FR 7672

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Six Years From When?

- Remember “identify” includes quantification.
- The six years runs from the date the overpayment is quantified not from the first suspicion of an overpayment.
- Operationally, this may be challenging.
- The proposed rule may change it.

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Bottom Line

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

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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

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Review Your Refunds

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Concurrent Surgeries

- At a teaching hospital, a surgeon is working with residents on three cases. One of the cases is being opened, one is being closed, and the third is in a key portion. The teaching physician was in the third case. Someone notes the following Manual language and believes fraud has been committed.

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Medicare Claims Processing Manual §100.1.2 – Surgical Procedures

2. Two Overlapping Surgeries

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

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Medicare Claims Processing Manual §100.1.2 – Surgical Procedures

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

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Medicare Claims Processing Manual
§100.1.2 – Surgical Procedures

A. Surgery (Including Endoscopic Operations)

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

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42 C.F.R. §415.172

- (a) ***General rule*** If a resident participates in a service furnished in a teaching setting, physician fee schedule payment is made only if a teaching physician is present during the key portion of any service or procedure for which payment is sought.
- (1) In the case of surgical, high-risk, or other complex procedures, the teaching physician must be present during all critical portions of the procedure and immediately available to furnish services during the entire service or procedure.

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42 C.F.R. §415.172

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

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The Refund Letter

- Do you ever send a “placeholder” letter?
- Who is it from?
- Who is it to?
- How much detail do you provide?
- What about small issues where cost of investigation exceeds overpayment?
- What don’t you say?

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Dr. C's Letter

- We **recently** discovered that one of our physicians **was committing billing fraud**. She was **not documenting services properly**. We **inadvertently** billed for these services. We did **a statistically valid sample**. We **have corrected the problem**.

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The Refund Letter

- “As part of our ongoing compliance process.”
- “More appropriate” is a great phrase.
- “Possible issues.”
- Reserve the right to recant.
- “Level we are confident defending…”
- Beware of “our attorney has told us…”
- “Refund” vs. “overpayment.”
- “Steps to improve…”

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What Do You Do With Copayments?

- Law is less clear.
- Size matters. (Would you bill the patient if they owed you the same amount?)
- State law.

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Do You Rebill or Refund?

- Rebilling generates timely filing issues.
- Refunding leaves bad claims data in the insurer’s system.
- For private payors, beware of your contract.
- Refund is the way to go.

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How Do Refunds Affect RACs?

- If you have sampled, no one claim has been “refunded.”
- This will be something to watch.
- Note this is an issue even if the audit is on a different problem.
- In any overpayment situation, always look at prior refunds/audits on the same issue.
- (Note tie-in to rebill/refund issue!)

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What About Private Payors?

- Contract (and manual??) control.
- Refund requirement is gov. only, but “health fraud” is a federal crime.
- State statute of limitations apply.
- State insurance law.
- Is Medicare Advantage a private payor?

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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.

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Relevant Rules?

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

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Physician Signature

- The rules will vary based on the payor, but Medicare doesn't require a signature.

  "11. Is the physician's signature required on each page of the documentation?

  No. The guidelines only state that the identity of the observer be legibly recorded."

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Signature Requirements

- If the signature is missing from an order, MACs and CERT shall disregard the order during the review of the claim (e.g., the reviewer will proceed as if the order was not received). *
- If the signature is missing from any other medical documentation (other than an order), MACs and CERT shall accept a signature attestation from the author of the medical record entry.

  - * This is wrong. See upcoming slides.

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“We don’t have written orders for our x-rays.”

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Program Integrity Manual, CMS Pub 100-08 §3.3.2.4, Signature Requirements *

- *If the signature is missing from an order, MACs and CERT shall disregard the order during the review of the claim (e.g., the reviewer will proceed as if the order was not received).*
- *If the signature is missing from any other medical documentation (other than an order), MACs and CERT shall accept a signature attestation from the author of the medical record entry*

*Manuals aren't rules

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Only Oral Orders

- If you don’t have a written order you are toast, right?
- Depends on several things, including the type of entity, the service in question, etc.
- Whoever wrote that failed to read the Halloween 1997 Federal Register issue.

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IDTFs Are Different

- “Some commenters have requested **the rationale for requiring specific written orders for tests performed by IDTFs while not imposing the same requirement on testing in physician offices**. The rationale for requiring testing by IDTFs to be ordered in writing by the treating physician is based in our (and, more specifically, HCFA’s contractors’) experience with IPLs. There have been instances in which IPLs have offered ‘free’ screening to Medicare beneficiaries in shopping malls and senior citizen centers.” – 62 Fed. Reg. 59048, 59072

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Conditions of Participation

- In some settings (Hospital, ASC), signatures and orders are COP.
- Conditions of Participation are not automatically Conditions of Payment.
- See the Supreme Court case *Universal Health Services v. Escobar*.

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Program Integrity Manual, Ch. 3, §3.1 – Introduction

- 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.

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COP Violations

- Regulations and Manual provisions contemplate that providers/suppliers will be paid through (and in some cases after) the date of termination. State Operations Manual, Ch. 3, §§ 3008-3008.1.
- There is no instruction for CMS to attempt to recoup payments made when a supplier was not in compliance with a condition for coverage.
- In Escobar, the Supreme Court said that in FCA cases, the test is materiality. Unclear how that test works in the context of an overpayment.

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Thank you!

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