Voluntary Disclosure of Noncompliance and Overpayments

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Today’s Presentation

• What is “noncompliance” and when does it mean you have an “overpayment”?
• This presentation is intended to assist with:
  • Determining noncompliance.
  • Quantifying overpayments.
  • Reporting and refunding overpayments.
Core Principles

- Treat the government fairly and require its representatives to treat you fairly.
- It is reasonable to get paid for what you do unless there is a CLEAR rule prohibiting it.
- If you have been overpaid, the money should be refunded.
- Mistakes are not fraud.

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.”

Refund Requirement

- The False Claims Act requires reporting and returning any Medicare/Medicaid overpayment within 60 days of “identification” of the overpayment.
- What is an overpayment?
- What is identification? That is, when does the 60 days start running?

Overpayment

- “Any funds that a person receives or retains under [the Medicare or Medicaid programs] to which the person, after applicable reconciliation, is not entitled under such title.”
- Many things are NOT overpayments.
  - Poor documentation.
  - Violations of COPs.
  - Reassignment problems.
Identification

- Not defined.
- House bill required reporting when you “know of an overpayment.”
- “Identification” seems to require quantification. Otherwise, how could you return the payment?
- Little clarity in CMS’s proposed rule on overpayments.

Report and Refund

- To whom?
- What information should you include?
- Form of refund – tips and warnings.
Example 1: E&M Coding

An internal documentation review finds:

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Question Authority

- Is it a requirement or a guideline?
- Medicare—ask if it is in the statute, regulations or Medicare Manuals.
- Get a copy of the rule in writing.
- Determine if the rule was properly promulgated.
- Analyze all arguments supporting and refuting their position.
- Just because they sound smart doesn’t mean they’re right.
What is the Relevant Law?

- “If it isn’t written, it wasn’t done,” right?
- Good advice, but not the law.
- Medicare payment is determined by the content of the service, not the content of the medical record.
- The documentation guidelines are just that: guidelines (although the Medicare contractor won’t believe that).

How Do We Figure Out If the Service Was Furnished?

- Ask.
  - The physicians.
  - Others (nurses, receptionists).
  - Secret shopper/shadowing.
- Schedules/time based billing.
- Patient complaints.
- Production data.
Audit Review Results - What Do They Mean?

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Our Facts:

- Physician D is a very hard worker; he is at the 75th percentile for RVUs.
- Physician C is a hard worker; he is at twice the 90th percentile for RVUs.
Preliminary Conclusions

- Dr. D is okay. Educate, don’t refund.
- Dr. C: Need more development. Begin interviews, etc.
- If you conclude the work wasn’t done, how do you calculate the amount?
  - Sample?
  - Calculation?

Example 2: Stark Law Noncompliance

- What is a “Stark Law Compliance” audit?
- Why are you auditing? When are you auditing? How are you auditing? Who is doing the auditing?
- Scope of the audit.
  - Single arrangement.
  - Single physician.
  - Multiple types of arrangements.
  - Fair market value issues.
Stark Law Compliance Audits

- When is the audit complete?
  - Rules are more finite than with documentation audits.
- At what point can you “identify” the overpayment?
- Factors to consider in calculating the overpayment.
  - Medicare FFS vs. other Medicare payment system.
  - Inpatient services.
    - Admitting physician.
    - Attending physician.
    - Consulting physician.
    - Hospitalist.
  - Outpatient services – ALL are DHS.
  - Reopening period.

Stark Law Compliance Audits

- Physician Fee Schedule: all DHS referred by the physician to the entity.
- Inpatient PPS.
  - Entire DRG payment?
  - None of the DRG payment if not impacted by the improper referral?
- Hospital OPPS: entire APC payment for improperly referred service.
- Impact of Medicare payment system on choice of refund “venue.”
Stark Law Compliance Audits

- Making a refund.
  - To whom?
    - Medicare Contractor.
    - OIG Self-disclosure Protocol.
- Process issues.
  - Timing.
  - Need for closure.

Example 3: Quality Concerns

- The Worthless Services Theory:
  - History of False Claims Act.
  - Provision of care that is tantamount to no care at all—failure to meet statutory standards.
  - Knowledge of provider.
Definitions

- HAC: hospital-acquired condition
- HCAC: health care-acquired condition
- POA: present on admission
- PPC: provider preventable condition
- OPPC: other provider preventable condition

NHC and Villa Spring Cases

- Nursing Home Failure of Care Cases.

- Examples of care that constitutes “worthless services.”

- Implied certification theory adopted in Villa Spring
Hospital Adverse Event Reporting

- Ensure that Hospital Acquired Conditions (HACs)/Preventable Conditions are reported.

- Recent OIG Report on Adverse Events.

- Coding/Risk Managers—What is your system for obtaining information and acting in a compliant manner?

The Preventable Serious Adverse Events Act, Act 1 of 2009

- Act 1 prohibits health care providers, including hospitals and nursing facilities, from knowingly seeking payment from a health payor or patient for: (1) a preventable serious adverse event ("PSAE"); or (2) for any services required to correct or treat the problem created by a PSAE.

- In addition, Act 1 requires a health care provider that unknowingly receives payment for services associated with a PSAE or for the services to correct the PSAE to immediately notify the health payor or patient and refund the payment within 30 days of discovery or receipt of payment, whichever is later.
What is a PSAE?

- A PSAE has 4 elements:
  1. The event was preventable. To be preventable, the event could have been anticipated and prepared for, but, nonetheless, occurred because of an error or other system failure; and
  2. The event was serious. The event is serious if the event subsequently results in death or loss of body part, disfigurement, disability or loss of bodily function lasting more than seven days or still present at the time of discharge from a health care facility; and
  3. The event was within the control of the health care facility. Control means that the health care facility had the power to avoid the error or other system failure; and
  4. The event occurred as a result of an error or other system failure within the health care facility.

- Act 1 also specifies that PSAEs "shall be included on the list of reportable serious adverse events adopted by the national quality forum or in a bulletin as provided under this act."

40 Pa.B. 6042, Saturday, October 16, 2010

Six Categories of PSAEs

- Surgery
- Product or Device Events
- Resident Protection Events
- Care Management Events
- Environmental Events
- Criminal Events and Unlawful Activities
Example 4: Noncompliance with the Medicare Conditions of Participation

- A hospital discovers many unsigned medical records, a violation of the conditions of participation. Must they refund all of the services?

42 CFR § 488.18 & 488.24

- If a supplier does not meet a condition for coverage, the state agency may:
  - Find that the supplier is in compliance, but with deficiencies not adversely affecting patient health safety; or
  - If deficiencies “are of such character as to substantially limit the provider’s or supplier’s capacity to furnish adequate care or which adversely affect the health and safety of patients” conclude that the supplier is out of compliance.
Program Integrity Manual
§3.1 - Introduction

Contractors must analyze provider compliance with Medicare coverage and coding rules and take appropriate corrective action when providers are found to be non-compliant. MR staff should not expend resources analyzing provider compliance with other Medicare rules (such as claims processing rules, conditions of participation, etc.). If, during a review, it is determined that a provider does not comply with conditions of participation, do not deny payment solely for this reason. Refer to the applicable state survey agency. The overall goal of taking administrative action should be to correct the behavior in need of change, to collect overpayments once identified, and deny payment when payment should not be made. For repeated infractions, or infractions showing potential fraud or pattern of abuse, more severe administrative action should be initiated. In every instance, the contractor's priority is to minimize the potential or actual loss to the Medicare Trust Funds while using resources efficiently and treating providers and beneficiaries fairly.

Key Points

- 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.
- Violations of the COPs are not an overpayment.
The Part B Side

- 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.

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.
Example 5: Medical Necessity

- A hospital discovers that a number of patients spent the night, but were in the hospital less than 24 hours. Compliance staff begin to investigate the medical necessity of the admissions, and ask whether a stay of less than 24 hours can be considered “inpatient.”

Legal Analysis: Who is an Inpatient?

Medicare Benefit Policy Manual
(CMS Pub. 100-02)
§10 - Covered Inpatient Hospital Services Covered Under Part A

An inpatient is a person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services.

Generally, a patient is considered an inpatient if formally admitted as inpatient with the expectation that he or she will remain at least overnight and occupy a bed even though it later develops that the patient can be discharged or transferred to another hospital and not actually use a hospital bed overnight.
Who is an Inpatient?

The physician or other practitioner responsible for a patient’s care at the hospital is also responsible for deciding whether the patient should be admitted as an inpatient. Physicians should use a 24-hour period as a benchmark, i.e., they should order admission for patients who are expected to need hospital care for 24 hours or more, and treat other patients on an outpatient basis.

However, the decision to admit a patient is a complex medical judgment which can be made only after the physician has considered a number of factors, including:

- The patient’s medical history and current medical needs;
- The types of facilities available to inpatients and to outpatients;
- The hospital’s by-laws and admissions policies; and
- The relative appropriateness of treatment in each setting.

Factors to be considered when making the decision to admit include such things as:

- The severity of the signs and symptoms exhibited by the patient;
- The medical predictability of something adverse happening to the patient;
- The need for diagnostic studies that appropriately are outpatient services (i.e., their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more) to assist in assessing whether the patient should be admitted; and
- The availability of diagnostic procedures at the time when and at the location where the patient presents.

Coverage of Inpatient Stays

- Admissions of particular patients are not covered or noncovered solely on the basis of the length of time the patient actually spends in the hospital. In certain specific situations coverage of services on an inpatient or outpatient basis is determined by the following rules:

**Minor Surgery or Other Treatment** - When patients with known diagnoses enter a hospital for a specific minor surgical procedure or other treatment that is expected to keep them in the hospital for only a few hours (less than 24), they are considered **outpatients** for coverage purposes regardless of: the hour they came to the hospital, whether they used a bed, and whether they remained in the hospital past midnight.
Preliminary Conclusion

- Strong legal defenses exist.
- Client prefers a cautious approach and wishes to refund.
- Issue: A new EMR only has records for the last 18 months.

Tips for Identifying (e.g., Calculating) Overpayments
How to Calculate an Overpayment

- Foolish inconsistency is the hobgoblin...
- What error rate triggers extrapolation obligations? (see 11/20/01 Rehnquist letter, http://oig.hhs.gov/fraud/docs/openletters/openletter111901.htm#N_1_)
- Who does the sample?
- Do you use Medicare’s methodology?

Sampling Issues

- Sampling unit (claim/patient/line item).
- Size.
- Simple versus stratified.
  - Variability.
  - Footballs and fish.
- Precision (.1 vs. .25).
- Confidence intervals.
**Sampling Issues**

- Midpoint or lower bound?
- $ per service. Different payors/changes over time.
- Offset underpayments?
- Universe.

**Universe**

- Is it Medicare only?
- Can you look at one year and project to three?
- How far back do you go?
  - Factual break.
  - “Statute of limitations.”
How Far Back Do You Go?

- False Claims Act says 6 years, or up to 10 if the government was not aware of a situation, BUT….
- Most billing errors are not false claims.
- The law requires the government to waive overpayments when the provider/supplier is “without fault” and recovery violates equity and good conscience.

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How Far Back Do You Go?

- If the denial based on medical necessity statute presumes “without fault” 3 years after the year in which payment was made.
- Service 12/20/03. Paid 2/1/04. Can recover until 12/31/07. Note: if paid 12/31/03, can recover until 12/31/06.
How Far Back Do You Go?

- Manuals indicate that claims may only be reopened after 48 months when there is evidence of “fraud or similar fault.”
- “Fraud or similar fault” requires some intentional wrongdoing.

Can You “Blame” Someone Else?

- Hospitals with an independent medical staff may try the “without fault” defense.
- Any service dependent on physician orders (lab/ambulance/PT) should consider using it.
- Outside consultant’s advice?
How Far Back Do You Go?

- The bottom line: unless you are guilty of fraud or similar fault, 48 months is a reasonable period to use.

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?
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.

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 . . .”
Should I Use the OIG Self-Disclosure Protocol?

- Take the government at its word: distinguish between “fraudulent” (intentionally or recklessly false) and innocent “erroneous” claims.
- The Compliance Program Guidance recognizes physicians make “honest mistakes” and these should be refunded without penalty.
- If someone wasn’t trying to take advantage of the system, I wouldn’t label the conduct as fraudulent.

Should I Use the CMS Self-referral Disclosure Protocol?

- Consider the amount of the potential overpayment.
- Need for timely resolution.
- Use of the SRDP in transactions where noncompliance was discovered during due diligence.
What About Private Payors?

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

Should I Ever Ask the Payor?

- Tough call. If you do:
  - Disclose all relevant facts.
  - Get it (or, better yet, give it) in writing. (Send it certified.)
  - Do not incriminate yourself.
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.

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.
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!)

Questions?

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Resources on Regulations, Manuals, and Guidance

Manuals Are NOT a Basis For an Overpayment

- “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.
Role of Documentation: The Law

“No payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.”

*Social Security Act §1833(e)*

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Role of Documentation: Guidance from CPT and CMS

- The CPT Assistant explains: “it is important to note that these are Guidelines, not a law or rule. Physicians need not modify their record keeping practices at all.”

*CPT Assistant Vol. 5, Issue 1, Winter 1995*

- Then HCFA, now CMS publicly stated that physicians are not required to use the Documentation Guidelines.
Role of Documentation: Guidance from CMS/HCFA

**Documentation Guidelines for Evaluation and Management Services Questions and Answers**

These questions and answers have been jointly developed by the Health Care Financing Administration (now CMS) and the American Medical Association (AMA); March 1995.

1. Are these guidelines required?
   No. Physicians are not required to use these guidelines in documenting their services.

Guidance from CMS/HCFA

However, it is important to note that all physicians are potentially subject to post-payment review. In the event of a review, Medicare carriers will be using these guidelines in helping them to determine/verify that the reported services were actually rendered. Physicians may find the format of the new guidelines convenient to follow and consistent with their current medical record keeping. Their usage will help facilitate communication with the carrier about the services provided, if that becomes necessary. Varying formats of documentation (e.g. SOAP notes) will be accepted by the Medicare carrier, as long as the basic information is discernible.
Guidance from CMS/HCFA

“6. How will the guidelines be utilized if I am reviewed by the carrier?

If an evaluation and management review is indicated, Carriers will request medical records for specific patients and encounters. The documentation guidelines will be used as a template for that review. If the documentation is not sufficient to support the level of service provided, the Carrier will contact the physician for additional information.”

Role of Documentation:
Guidance from CMS/HCFA

“7. What are my chances of being reviewed?

Review of evaluation and management services will only occur if evidence of significant aberrant reporting patterns is detected (i.e., based on national, carrier or specialty profiles). Our reviews are conducted on a ‘focused’ basis--there is no random review.”

• Documentation is relevant only if there is doubt that the services were truly rendered.