Drug Billing Compliance in Provider Settings: Auditing Strategies

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Goals

- Learn the benefits, opportunities, and challenges to conducting a drug billing risk assessment
- Understand and evaluate accepted approaches for reviewing complex unknown risk in an active government audit environment
- Assess the distinct stages of assessment and review which are unique to drug billing compliance

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Presentation Sections

1. Topics in drug billing compliance
2. Conducting a drug billing audit
3. Possible outcomes for a drug billing audit

- Note 1: This lecture will focus on the principles of pharmacy billing compliance in a provider setting and not retail pharmacies – though principles discussed can be used in retail pharmacy compliance
- Note 2: This lecture will principally use Medicare reimbursement principles as a guide for pharmacy billing compliance

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Themes

1. Compliance begins with the order
2. An audit should review the life cycle:
   - From order to remittance
3. Not all deficiencies in an audit result in an "overpayment"

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Topics in Drug Billing Compliance

- HHS OIG Workplan 2013 & 2014:

Payments for Outpatient Drugs and Administration of the Drugs

Billing and Payments. We will review Medicare outpatient payments to providers for certain drugs (e.g., chemotherapy drugs) and the administration of the drugs to determine whether Medicare overpaid providers because of incorrect coding or overbilling of units. Context—Prior OIG reviews have identified certain drugs, particularly chemotherapy drugs, as vulnerable to incorrect coding. Providers must bill accurately and completely for services provided. (CMS's *Claims Processing Manual*, Pub. No. 100-04, ch. 1, §§ 70.2.3.1 and 80.3.2.2.) Further, providers must report units of service as the number of times that a service or procedure was performed. (Chapter 5, § 20.2, and ch. 26, § 10.4.) (OAS; W-00-12-35576; various reviews; expected issue date: FY 2014; work in progress)

*2014 Work Plan Reference: Pg. 22, Medicare Part A and Part B

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Topics in Drug Billing Compliance

- HHS OIG Workplan 2014

Covered Uses for Medicare Part B Drugs (New)

Quality of Care and Safety. We will review the oversight actions CMS and its claims processing contractors take to ensure that payments for Part B drugs meet the appropriate coverage criteria. We will also identify challenges contractors face when making coverage decisions for drugs. Context—If Part B MACs do not have effective oversight mechanisms, Medicare and its beneficiaries may pay for drugs with little clinical evidence of the drugs' safety and effectiveness. Medicare Part B generally covers drugs when they are used to treat conditions approved by the Food and Drug Administration, referred to as "on-label" uses. Part B may also cover drugs when an "off-label" use of the drug is supported in major drug compendia or when an off-label use is supported by clinical evidence in authoritative medical literature. (Social Security Act, § 1861(t).) (OEI; 03-13-00450; expected issue date: FY 2014; work in progress)

*2014 Work Plan Reference: Pgs. 22-23, Medicare Part A and Part B

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Topics in Drug Billing Compliance

1. Is there a written drug order?
2. Is there documentation of administration of the drug?
3. What are the billing units per amount of drug?
4. Are the units billed equal to the amount administered?
5. Is wastage billing allowed?
   - (Does the wastage amount need to be identified on the claim?)
6. If there is a billing error, did it result in an overpayment?

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Conducting a Drug Billing Audit

- Questions to consider:
  - Which drugs will be audited?
    - Consider: specific high-volume and high-value drugs
    - Drugs identified in OIG Workplan and national audits (e.g., Herceptin)
  - What time period?
    - Baseline audit ("are we doing it correctly today?"): within current fiscal year
    - Routine not-for-cause: within current fiscal year or consider two fiscal years to analyze what happens when changes in pharmacy chargemaster occur
    - Clean-up not-for-cause ("this is a high risk area; what is our exposure?"): consider statute of limitations period (generally 6 years)
    - For-cause: time period errors are suspected or consider statute of limitations period
  - How large is the sample?
    - Probe review: 20-40 similar units
    - Probes for each drug? Each year? Patients per year?
    - Local circumstances will drive sample size and design

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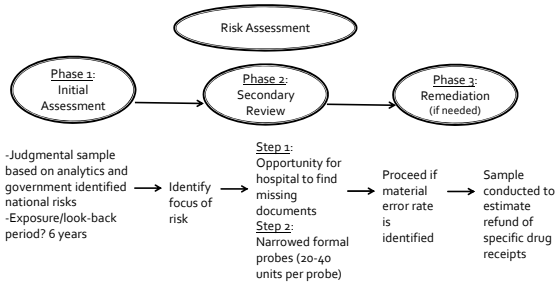
Conducting a Drug Billing Audit

Phases in Compliance Auditing



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Conducting a Drug Billing Audit

- Drug billing audits may need to be conducted in several phases
- For the first phase, generally use a "no assumptions" approach
  - "If it isn't documented, then it didn't happen"
  - This approach will provide a window into immediate risk exposure from an external audit, how well documents are provided, and allow the broadest recommendations for improvement
- For the second phase, dig deeper to find missing documents or confirm with clinicians what is implied in medical record but not explicit
- For the third phase, determine whether error caused a financial impact

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Conducting a Drug Billing Audit

- Documents needed:
  - Medical record
    - Physician's order
    - Administration of drug
    - Shadow charts?
  - Claim forms
  - Detailed charges captured for generating claim form
  - Remittance advice (what was paid)
  - Miscellaneous?
    - Pharmacy reconciliation reports

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Conducting a Drug Billing Audit

- Understand the documentation landscape
  - Audit identifies missing documents associated with drugs often not known to be missing until audited
- Are records electronic or paper? Or combination of both?
- If crossing time period into EMR, when did EMR go live? Did it go live for all departments or was it staged?
- If records are in EMR, do auditors have access to the right parts of the EMR?
  - Is there access to the e-medication administration records (MARS)?
- Are there legacy issues relating to:
  - Stamped signatures on physician order forms?
  - Possible shadow charts outside of EMR?
  - Series accounts billed consistently though dosage dropping?

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Conducting a Drug Billing Audit

- Items to know about the drug being audited:
  - Drug J Code (HCPCS)
  - Generic Drug Name
  - Proprietary Drug Name
  - On Label Indication
  - Off Label and/or Compendial Listing
  - How Supplied
  - Units for Billing
  - Any applicable NCDs or LCDs?

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Conducting a Drug Billing Audit

- Notes on Billing Units:
  - When billing drugs, units of service must be billed in multiples of the dosage specified in the full HCPCS descriptor.
  - If the dosage given is not a multiple of the HCPCS code, the provider rounds to the next higher unit in the HCPCS description for that code.
  - For example, if 2.5 milligrams of Zoledronic Acid is administered, it is appropriate to bill for 3 units, as the HCPCS defines the unit for Zoledronic Acid as 1 milligram.

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Conducting a Drug Billing Audit

- Notes on Billing for Wastage:
  - If after administering the prescribed dosage of any given drug, the provider must discard the remainder of a single-use vial or other package, Medicare may cover the amount of the drug discarded along with the amount administered. The following elements must be followed in order for the discarded amount to be covered.
    - 1. The vial must be a single use vial. Multi-use vials are not subject to payment for any discarded amounts of the drug.
    - 2. The units billed must correspond with the smallest dose (vial) available for purchase from the manufacturer(s) that could provide the appropriate dose for the patient.

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Conducting a Drug Billing Audit

- Notes on Billing for Wastage:
  - Example:
    - HCPCS J0152, Injection, adenosine for diagnostic use, 30 mg
  - Doses available from the manufacturer include:
    - 6 mg, 12 mg, and 60 mg
  - The amount prescribed for the patient is 70 mg. If the provider uses two 60 mg vials to administer the dose, the provider may only bill 3 units (rather than 4 units) as the doses available from the manufacturer allow the prescribed amount to be administered with a 60 mg vial (2 units) and a 12 mg vial (additional unit).

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Possible Outcomes for a Drug Billing Audit

- *Think through the potential errors and implications ahead of time*
- Not all errors result in "overpayment"
- Distinction between:
  - Condition of Participation error – usually no overpayment
  - Condition of Coverage/Payment error – possible overpayment

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Possible Outcomes for a Drug Billing Audit

- Conditions of Participation:
  - Administrative requirements for participating in a federal health care program
  - Often organizational requirements rather than payment or service specific
  - *Example*: All documents must be completed (including signed) within 30 days after discharge
  - Noncompliance with conditions of participation risk administrative sanctions, but noncompliance usually does not result in a payment impact
- Conditions of Coverage/Payment:
  - Requirements in order to received reimbursement for specific items and services
  - Often very detailed rules about specific items and services
  - *Example*: Payment for drug only allowed when it is ordered for a medically accepted use
  - Noncompliance with conditions of coverage/payment may result in receiving an "overpayment" if item or service should not have been billed

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Possible Outcomes for Drug Billing Audit

- What could be specific dispositions within a drug billing audit?
  - Missing order
  - Unsigned verbal order
  - Unapproved use
  - No evidence of administration
  - Not administered as ordered
  - Over-billed units
  - Under-billed units
  - Missing record
  - Miscellaneous (always leave room for the unknown!)

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Possible Outcomes for Drug Billing Audits

- Are the errors conditions of participation or conditions of coverage/payment errors?
- If conditions of participation error, then identify documentation improvement needs
- If conditions of coverage/payment error, then check remittance advice:
  - Did the provider receive a bundled payment?
    - If so and no outlier payment, then likely no overpayment (assuming drug is not driving the bundled payment)
    - If so and received an outlier payment, then drug billing error may have contributed to receiving outlier payment
  - Did the provider receive a pass-through payment?
    - If so, then drug billing error may have contributed to receiving outlier payment

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- Questions/Discussion

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