Pharmacy Billing Compliance

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Goals

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

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”
OIG Workplan 2013:

Payments for Outpatient Drugs and Administration of the Drugs:

“We will review Medicare outpatient payments to providers for certain drugs and the administration of the drugs (e.g., chemotherapy drugs) to determine whether Medicare overpaid providers because of incorrect coding or overbilling of units. 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 Medicare Claims Processing Manual, Pub. 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 (ch. 5, § 20.2, and ch. 26, § 10.4.).”

Off-Label Use of Medicare Part B Drug:

“We will review off-label (prescribed for a condition that is not listed on the product’s label) and off-compendia use of certain Medicare Part B prescription drugs and determine the extent to which specified compendia provide support for coverage. We will also identify CMS oversight mechanisms related to off-label use of drugs. For prescription drugs to be covered, Federal law generally requires that they be prescribed according to medically accepted indications, such as those approved by the Food and Drug Administration (FDA) or supported in one or more of the authoritative drug compendia identified by the Secretary of Health and Human Services (HHS). Therefore, most drugs are covered when used off-label as long as one of the designate compendia has determined that there is sufficient evidence that the drug is safe and effective for treating the condition.”

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?
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)
- 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

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

Understand the documentation landscape
- 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)?
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?

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.

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.
**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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**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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**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
**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

**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
  - Misc (always leave room for the unknown!)

**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 no 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
- Questions/Discussion