


An Update on Operational Issues: Audits




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Being Prepared for Pharmacy Audits Six Top Tips

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*Member refers to plan member, an individual eligible for prescription drug benefits under a plan.
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Being Prepared for Pharmacy Audits Six Top Tips

1. Fraud, Waste and Abuse training
2. Monitoring of Staff for OIG Exclusion
3. CMS PDE/DIR Audits
4. Use the correct Prescriber Identification
5. Proper submission of Compounds
6. Records Retention


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FWA Training

- CMS has an annual requirement that all pharmacy personnel complete FWA training
- PBMs may require a specific training or allow attestation of other training materials to be utilized
- Training should include fundamental compliance areas:
 - The Medicare Part D prescription drug benefit;
 - Relevant laws and regulations governing the benefit;
 - Methods used to help identify and mitigate potential compliance issues and/or potential FWA;
 - Risk areas vulnerable to FWA;
 - Employee responsibility for reporting issues;
 - How to report potential compliance and FWA issues;
 - The role played by the Medicare Drug Integrity Contractors (MEDICs), CMS, and law enforcement agencies

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■ OIG Exclusion Verification

- Medicare. Section 50.2.1.2 of the guidance provides
"The Sponsor should obtain certifications from first tier entities, downstream entities, and related entities that these entities will review the OIG and GSA exclusions lists upon initially hiring and annually thereafter to ensure that any employee or manager responsible for administering or delivering Part D benefits is not excluded from Federal health care programs. The Sponsor should likewise obtain certifications that if an employee of the first tier entity, downstream entity, or related entity responsible for the administration of delivery of any Part D benefits is on such lists, that employee will immediately be removed from any work related directly or indirectly to all Federal health care programs and the entity will take appropriate corrective actions."
- Contractual obligation with Plan Sponsors and PBMs

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CMS Audits

The guidance provides that CMS or its designees (such as MEDICS) may audit plan sponsors or their "subcontractors." See § 50.2, §.4. During those audits "CMS may inspect and audit any pertinent contracts, books, documents, papers, and records..." CMS audits may review "any information needed to determine compliance with the Part D contract and the Part D regulation, such as copies of prescriptions, invoices, pharmacy licenses, claims records, signature logs, purchase records, contracts, rebate and discount agreements, as well as, interviews of the staff."

- CMS, Medicare Part D plan sponsors, or designated agents also audit through requests made to Plan Sponsors and downstream entities – these audit have increased in scope and duration of time
- CMS and/or subcontractors
- PDE Validation Audits
- Financial Audits
- Types of information being requested
 - Hard copies of prescriptions
 - Computer submission screens
 - Signature Logs
- Time allowance for response is typically short by virtue of chain of request; CMS subcontractor – Plan Sponsor – PBM – Pharmacy
- Non-Compliance is failure to comply with a federal guideline – potential actions for non-compliance
 - Chargeback
 - Corrective Action Plan
 - Probation or Termination of contract

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Invalid "Dummy" DEA Numbers

- HHS-OIG released a summary June 2010 (OEI-03-09-00140) – Invalid Prescriber Identifiers on Medicare Part D Drug Claims
 - \$1.2 billion in Medicare Part D prescription drug claims contained invalid prescriber identifiers in 2007
 - Ten invalid identifiers accounted for 17 percent of the drug claims with invalid prescriber identifiers
 - Medicare drug plans and enrollees paid pharmacies \$237 million in 2007 for drug claims that contained these top 10 invalid identifiers
 - AA000000, AB1111119, ZZ4567890, AB1234563, AA1111119, AB5555555, CC1462667, AS1111119, AS1234563, AM1111119
- CMS released a memo August 13, 2010 to Medicare Part D Plan sponsors reacting to the HHS-OIG summary
 - Analysis of 2009 data demonstrated that the issue noted in the 2007 data with use of the invalid DEA had continued and needed to be addressed

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■ National Compendia

- Under CMS rules, Part D plan sponsors cannot cover Part D drugs prescribed for off-label uses unless those appear in one of three Medicare-approved drug compendia — the United States Pharmacopeia Drug Information, the American Hospital Formulary Service Drug Information and the Drugdex System. (USPDI and Drugdex are now combined as Micromedex)
- Now, effective Jan. 1, 2009, Part D covers off-label drug treatments for cancer if they are listed in any CMS-approved compendia used for determining coverage under Part B. Moreover, effective in 2010, all compendia must have a publicly transparent process for evaluating drug therapies and must disclose any conflicts of interest.
 - NCCN

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■ Compounded Medications

- CMS regulation states Compounded Medications must be covered by the Plan Sponsor
- CMS regulation also states that medications must maintain the definition of a Part D drug (compensial use)
- Excluded Medications
- Changing route of administration – may be clue of non-compensial
- Single Ingredient Submission vs. Multi-Ingredient Submission
- NCPDP (2012) change to D.0 to Multi-Ingredient (ability to accept payment for approved items only)

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■ Records Retention

- Chapter 9 states:
 - "... cooperation includes providing CMS and/or the MEDICs with access to all requested facilities and records associated in any manner with the Part D program for 10 years (6 years for RDS Sponsors) from the end of the final contract period or completion of an audit, which ever is later. In cases when there is a termination, dispute, or allegation of fraud or similar fault by the Part D plan Sponsor, the record retention requirements may be extended to 6 years from the date of any resulting final resolution of the termination, dispute, or fraud or similar fault."
- 42 CFR 423.505(e)(4)(ii)
- It's not just 10 years like some believe ...
 - 6 years for RDS
 - 10 years from end of final contract period
 - 10 years from completion of an audit
- Records
 - Contracts / Provider Manuals
 - Prescription Records (electronic acceptable)
 - Signature Logs
 - Patient Records
 - Invoices

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Questions???

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