



**HCCA's 12<sup>TH</sup> ANNUAL COMPLIANCE INSTITUTE**

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**As the Pharmacy World Turns.....How Broad  
is the Scope of Pharmacy Compliance?**

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**Pharmacy Compliance Areas of Risk**

- I. Fraud and Abuse
- II. Billing
- III. Regulatory Changes
- IV. Diversion



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## Why Pharmacy Compliance?

- Medicare Part D estimated costs over \$243.7 billion in ten-year period (2004-2013)
- Medicaid costs over \$300 billion each year
- OIG reported \$43 Billion in savings from fraud and abuse enforcement in 2007
- As of September 30, 2006, Recovery Audit Contractors (RAC) audits had identified \$303.5 million in improper payments
- **More Fraud and Abuse Projects Planned for 2008**
  - Recent headline: “CMS Already Planning Anti-Fraud Measures For Third Year of Drug Benefit”
  - RAC audits are coming - preparing for risks instead of always reacting to fires
    - Billing, Charging, Coding Issues



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## Fraud and Abuse

- New Medicare Rule Mandates Pharmacy Fraud & Abuse Training
  - By Jan 2009, Part D plans must require pharmacy training
  - Plan can offer own training or delegate choice to pharmacy
    - But plan “must maintain appropriate oversight” of training
    - CMS will verify training through audits
    - Plans must get “training logs and copies of attestations” from pharmacies
- Pharmaceutical Gifts
  - Taking a hard stand
    - Drug samples
    - Pens
    - Gifts



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## Billing Risks: Hospital

- National Drug Code Billing
  - Currently State requirement
  - Medications dispensed to outpatient's
  - Reported rebates
- Erythropoietin Billing
  - Correctly applied modifiers on claim
    - EA, EB, EC
  - Reporting of hematocrit or hemoglobin directly on claim
- Vaccinations/Self Administered Drugs
  - Billed through Part D
  - Hardship on patients



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## Billing Risks: Retail Pharmacy

- Process for prescription reversals
  - Partial fills
  - Return to stock
- Third Party Liability
  - Dual eligibility
  - Credit balances
- Ensure Billing Correct Medication
  - Brand vs. generic



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## Regulatory Changes

- NPI Implementation
  - May 23<sup>rd</sup> deadline
- Retail Pharmacy Accreditation
  - Requirement of MMA of 2003
- Pharmacy Own Brand
  - FDA required reporting
  - Implementation date of 1-1-2009
- E-Prescribing
  - Currently optional
  - Clear, accurate and understandable



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## Regulatory Changes cont.

- Tamper Resistant Prescriptions
  - Delayed deadline – April 1, 2008
  - Applicable, regardless of whether Medicaid is primary or secondary payer
  - One or more industry-recognized features designed to prevent unauthorized copying of a completed or blank prescription form
  - One or more industry-recognized features designed to prevent the erasure or modification of information written on the prescription by the prescriber
  - One or more industry-recognized features designed to prevent the use of counterfeit prescription forms



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## Diversion

- Identify most common drugs of abuse
  - Diversion trends – recreational drugs with a street value
- Ensure sites are meeting all requirements of law (21 C.F.R. 13021.71(a))
  - Effective controls and procedures are in place to guard against theft and diversion of controlled substances
  - Ongoing assessment of the effectiveness and efficiency of controls
  - Reporting theft or substantial loss
- Have safeguards in place to deter potential diversion
  - Educate staff on simple steps to detect diversion
  - Ensure sites are complying with government, regulatory and company policy



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## Questions



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