Hot Topics: Pharmacy Perspective

HCCA
Upper Midwest Regional Conference
September 14, 2012

Pharmacy Hot Topics

- 2013 Medicare Part D Rule Changes
- REMS, Prescription Drug Monitoring Programs
- Drug Diversion
- Board of Pharmacy Rules
- ePrescribing and Electronic PA (Prior Auth)
- Medicaid Reimbursement
- False Claim Audits
- Healthcare Reform
2013 Medicare Part D Claim Requirements

- **Pharmacy Service Type (147-U7)**
  - Use for code 1 Community Retail Pharmacy
  - Seven other options for other pharmacy types
- **Patient Residence (384-4x)**
  - Use code 1 for Home in Retail Pharmacy settings
  - Fourteen other options for other service types
- **Short Cycle Dispensing -LTC**
- **Valid Prescriber NPI**
  - CMS will not pay Part D plans for a claim unless the Prescription Drug Event (PDE) contains a valid prescriber NPI
  - Can alert a pharmacy through a number of rejection codes with standard pharmacy overrides
  - Can alert pharmacy through a number of standard paid message codes alert the pharmacy that the claim is under review

Valid Prescriber Edits

- NPI Status (Deactivated / Expired)
- **NPI Type (Organization Type 11 vs Individual type 1)**
- NPI Not Found
- Last name Mismatch
- DEA Not Found for controlled drugs
- DEA Status Expired for controlled drugs
- DEA Authorization (Schedule Validity)
- Out of State DEA for controlled drugs
- Organization DEA Submitted for controlled drugs
- State License Not Found
- OIG Exclusions
- State License Status Expired
- State License Furnishing Privilege
- State Medicaid Exclusions
- Prescriber Deceased
REMS, Prescription Drug Monitoring Programs

- Elements:
  - Medication Guide (MedGuide)
  - Patient Package Insert (PPI)
  - Communication Plan
  - Elements to Assure Safe Use (ETASU)
    - Pharmacy training registry
    - Prescriber training registry
    - Patient training registry
    - Restricted distribution (Distributor Registry)
    - Audit and Monitor
  - iPLEDGE (Training/Fines Penalties)

Drug Diversion

- Typical modes of diversion include: internal theft, script fraud, script altering, doctor shopping, and robbery.
  - CDC estimates 2 Million are currently using painkillers non-medically
  - 5,500 people start to misuse prescriptions every day.
  - Estimated 40 people die each day from overdoses.
  - For the first time in history, in 2010, drug-induced deaths surpassed motor vehicle-related deaths
  - More people abuse prescription drugs than the combined number of those who use cocaine, heroin, and meth.
  - The National Drug Control Strategy and the CDC call out prescription drug abuse as an ‘epidemic’.
  - Currently, the distribution and dispensing of oxycodone is a primary focus of DEA Tactical Diversion Squads. They are monitoring distribution quantities to retail pharmacies, as well as tracking loss reports in order to identify pharmacies and doctors of interest.
  - 49 states have been authorized and 40 states have some sort of Prescription Drug Monitoring Programs.
Board of Pharmacy

- Substance Overprescribing / Abuse of Narcotics
  - Expansion of Prescription Drug Monitoring requirements
  - PSE – increasing reporting requirements, pharmacist counseling, lowering of limits
  - Scheduling abused drugs such as Tramadol and Hydrocodone to a Schedule II
  - Considering decreasing the quantities allowed on initial narcotic prescriptions

Diversion, Thefts and Pharmacy Security
- Increase scrutiny to ensure pharmacies have appropriate security to protect narcotics from internal theft
- DEA focusing on watching that pharmacies fill prescriptions from legitimate providers for legitimate medical needs

Pain Clinics “Pill Mills "on the Rise
Board of Pharmacy Con’t

- Updates to Practice Acts to accommodate
  - New technology and automation
  - Changing practice models – MTM, Immunizations, Biometric services, Non-traditional pharmacy formats

- Safety and Quality
  - Staffing, coupons, workload and other challenges that could potentially affect public safety
  - Discussions aimed at prescription error analysis and reporting

- Technicians
  - Regulations on training and certifications, background checks, duties allowed
  - Ongoing discussions on ratios - technicians allowed per pharmacist

ePrescribing and Electronic PA

- ePrescribing: NCPDP 10.6 Script Standard required by 10/2013. New features:
  - Change
  - Cancel
  - Renewal
  - RxNorm
  - Standard SIG codes
  - Controlled Substance

- Electronic Prior Auth (ePA)
  - November 2012 NCPDP is expected to approve a ePA transaction between the pharmacy<>Prescriber<>Health Plan
Pharmacy Reimbursement
Medicaid + ?

1. AWP
2. WAC
3. SMAC
4. AMP
5. AAC + COD
6. NADAC + COD
7. NARP

False Claim Audits

- CMS: CERT, RAC, ZPIC, MIC
- Commercial (PBMs and Plans)
- Contracted Audit companies
- Medicare Part D Plans
- Medicaid Agencies
- DEA (Controlled Substances)
- FDA (Recalls, REMS, PSE)
- DOD (Tricare)
- OIG (Sanctioned prescribers and providers)
False Claim Audits-What’s Audited

- Over-billing of quantity and/or days’ supply prescribed
- Missing prescriptions
- Missing signatures
- Not reversing returns to stock
- Invalid prescriber ID's submitted
- No SIG: UAD/TAD documentation
- No documentation for Dispensed As Written (DAW I)
- Billing of unauthorized refills
- Billing under expired prescriptions
- Dispensed discontinued NDC
- Billing Secondary as Primary
- Billing Part D vs. B vs. Hospice/LTC

Healthcare Reform Impact

- Expansion with Pre-existing condition coverage
- Medicaid optional expansion
- Insurance exchange impact patient plan changes
- Medical Home/Transitional Care Pharmacist-delivered MTM and other services
Hot Topics:
Hospital and Clinic Perspective

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Allina Health “Hot Topics”

• Privacy and Security
• Controlled Drug Diversion
• Billing Compliance Issues
• Ethical Relationships with Industry
Clip


Investigation Process

- System-wide approach
  - Various methods for reporting
    - Report/Allegation Occurs
- Involve Key Contacts
- Retrieve Data
- Perform Investigation
  - Review of data
  - Discussion with employee
- Conference Call with key players
  - Consistent discipline process
Controlled Drug Diversion

- Hospitals
- Clinics
- Retail Pharmacy
- Ambulance Transportation
- Home Care and Hospice (patient home)

Controlled Drug Diversion

- System-wide Workflow and Communications for Suspected Diversions
- E-Learning (identified access to controlled substance)
  - Education on recognizing and reporting
- Risk Assessment
  - Development and implementation of risk assessment tools
- Gap Analysis
  - Implementation and scoring mechanism
- System-wide Communication Strategy
Clinic Topics

• Established vs. New Patients

• Billing “Incident to”
  - Ensuring regulatory requirements are met
  - Pro-fee billing vs. hospital based

• DME Billing
  - Supplier Standards

• “Copy and Paste” functionality
  - Electronic medical record

Hospital Topics

• National Drug Code (NDC) Medication Reporting
  - Rebates

• Patient Meeting “Admission criteria”
  - Assessment with 24 hrs.
  - Learning's Institutionalized
Specialty Area Topics

- Oxygen Billing
  - Qualifying test for Oxygen Therapy

- CPAP Billing
  - Supplies
    - meeting re-order billing rules

- Hospice Care
  - Contracts with referring providers

Ethical Relationship with Industry

- Policy Development and Implementation
  - System-wide Education

- Applied to All Employees

- Employed Providers
  - Yearly reporting
Hot Topics: Health Plan Perspective

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Top of the list

- Compliance program effectiveness
- Fraud, waste, abuse (program integrity)
- Data: accuracy, timeliness, completeness
- Delegate oversight
  (first tier and downstream entities)
- Privacy and data security
Compliance Program Effectiveness

- In sync with expectations?
  - 2012 CMS program audit protocols for Medicare Advantage
  - Medicare Managed Care Manual and Prescription Drug Benefit Manual changes effective 7/20/12
  - State contractual obligations

- Communication
  - Staff, leadership, and board awareness and responsibilities
  - Gap analysis and status
  - Action plan, subsequent monitoring, progress

Fraud, Waste, Abuse

- In sync with regulatory expectations?
  - 2012 CMS program audit protocols for Medicare Advantage
  - Medicare Managed Care Manual and Medicare Prescription Drug Benefit Manual changes effective 7/20/12
  - State contractual obligations

- Awareness and responsibilities
  - Commitment to prevention and detection
  - Staff, leadership, and board
  - Delegates, vendors, network providers
  - Members are partners
Data
Accuracy, Timeliness, Completeness

- In sync with regulatory expectations? (just a sample)
  - CMS: data validation audits, risk adjustment data validation, plan star rating measures
  - State encounter data
- Awareness and responsibilities
  - Commitment to “quality in, quality out”
  - Staff and leadership
  - Delegates, vendors, network providers

Delegate Oversight

- In sync with regulatory expectations?
  - 2012 CMS program audit protocols for Medicare Advantage
  - Medicare Managed Care Manual and Medicare Prescription Drug Benefit Manual changes effective 7/20/12
  - State contractual obligations
- “Delegates are us”
  - Staff and leadership awareness and responsibilities
  - Gap analysis and status
  - Performance expectations clearly communicated
  - Monitoring and corrective action
Privacy and Data Security

- In sync with…
  - Regulatory expectations: HIPAA, HITECH, OCR, State privacy laws
  - Contractual obligations: the plan’s and the other parties’
  - Members’ expectations
- Commitment to knowing what is received, stored, used, and shared, as well as how and why
  - Staff, leadership and board
  - Delegates, vendors, network providers
  - Members

Hot Topics:
Device Industry Perspective

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Hot Topics - Device

Sunshine Act and Beyond
“The Crushing Rush to Report”

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Hot Topics Panel - Device

Physician Payments Sunshine Act
(*Section 6002 of Patient Protection and Affordable Care Act*)

- requires disclosure of any payment or transfer of value over $10 to physicians or teaching hospitals

- HHS to establish by October 2011 reporting procedures and procedures for making information available to public

- Data collection to start January 1, 2012 with first report March 2013

- Failure to report may result in fines up to $150,000
Hot Topics Panel - Device

- CMS issued proposed rule in December 2011 and pushed back data collection to January 2013
- Various stakeholders submitted more than 300 comments to proposed rule
- No further word from CMS
- September 12 - Senator Kohl to convene roundtable discussion “Let the SunShine In: Implementing the Physician Payments Sunshine Act”

Hot Topics Panel - Device

Sunshine Beyond the U.S.
- A growing number of countries requiring or contemplating disclosure similar to Sunshine
  - Korea
  - Australia
  - Greece
  - Japan
  - United Kingdom
  - Canada
  - France
- Disclosure requirements vary by country
Hot Topics Panel - Device

Enforcement Climate

“It’s Lonely at the Top”

Hot Topics Panel - Device

• Enforcement community’s continued focus on “Responsible Corporate Officer Doctrine” and individual liability

• Park Doctrine – a corporate officer in a position of authority to prevent or correct an FDCA violation, but fails to do so, may be convicted of misdemeanor even if unaware of violation

• After misdemeanor conviction or plea – exclusion from federal healthcare program or prison
**Hot Topics Panel - Device**

**Examples of Park Doctrine Prosecutions**

- CEO of Forest Laboratories threatened with exclusion in April 2011, but government backed away four months later

- Four former Synthes execs received prison time after pleading to misdemeanor

- In July 2012, three former Purdue Pharma execs excluded after misdemeanor plea

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**Hot Topics Panel – Device**

**Factors to be considered**

- Individual’s position in company
- Individual’s authority to correct or prevent
- Individual’s knowledge of or participation in violation
- Actual or potential harm to public
- Pattern of illegal behavior or failure to heed prior warnings
- Severity of violation