

Pharmacy Compliance: More than Taking Two Aspirins and Calling a Doctor in the Morning

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Objectives

- Importance of pharmacy compliance
- Pharmacy compliance risks between the hospital and retail environments
- Auditing and monitoring ideas

Why Pharmacy Compliance?

- Know your Risk – it's the right thing to do
 - Due diligence in billing
 - Pharmacy compliance is large, complex and constantly changing
- Increase Government Enforcement - focus on fraud, waste and abuse
 - Corporate Integrity Agreement (CIA)
 - DRA – OIG rec'd additional 25 million in funding
 - Unprecedented efforts by CMS: 8-100 in program integrity
 - Funding increase – 5 million in 2007 – 75 million in 2008

Why Pharmacy Compliance? continued

- Medicare Part D
 - CMS issued fraud, waste and abuse guidance in 2006 (applies to pharmacies)
 - Part D audits by Medics
 - Recommendation are becoming requirements for pharmacies in a plans network contract
- Medications touch many segments in a patients episode of care

Risk Areas for Retail Pharmacy Issues

- Partial fills
- Billing for scripts that are never picked up
- Billing multiple providers
- Return credit balances to patients and payers
- HIPAA
- Diversion
- Reimbursement basis

Risk Areas for Hospital and Specialty Areas Pharmacy Issues

- Billing for undocumented medication
- Billing systems
- Reimbursement basis
- HIPAA
- Medication diversion
- Outpatient medication administration
- HCPCS coding

Resources

- OIG Workplan
<http://www.oig.hhs.gov/publications/workplan.html>
- Corporate Integrity Agreements
 - Requirements
 - Risk areas
- Medicaid and Medicare Updates
- NACDS Guidance (National Association of Chain Drug Stores)
 - Model Compliance Program Manual
- OIG Advisory Opinions

OIG Workplan

Retail Based

- Medicare Part D
- Medicaid prescription drugs
- Specific medication regulations
- Third party liability/Dual eligibility
- Drug access through prior authorization

Provider Based

- Comparison of CAP to ASP
- Medicare Part D
- Specific medication regulations

Auditing Tips

- Review Chapter 9 of the Prescription Drug Benefit Manual
 - Know your audit rights
 - Know your audit requirements
- Ensure pricing methodologies documented
 - Documentation trail exists for calculations performed
- Ensuring identified medication risks from work plan are incorporated into program

Medicaid and Medicare

Retail

- Ensure NDC billing is accurate
- Excluded Providers/State List
- Prescription Documentation Requirement
- Sample Medications

Provider

- Ensure APC billing is accurate
- Excluded Providers
- Sample Medications

Auditing Tips

- Ensure all billing methodologies are compliant with legislation
 - Keep up-to-date on changes in legislation
- Ensure products are being reimbursed
 - Under the correct legislation
 - Using correct reimbursement basis

Retail Provider-Specific Issues

Pharmacy Issues Within A Retail Setting

- Partial fills of prescriptions
- Handling and dispensing of sample medications

Auditing Tips

- Process in place to reverse charges
- If dispensing samples, P&P in place to support process

Pharmacy Issues within a Retail Setting continued

- Signature Logs
- Consistency of P&P between locations
- HIPAA

Auditing Tips

- Process in place to capture all prescription pick-ups
- Ensuring documented P&P along with employee attestation of knowledge
 - most stringent law is followed – state

Pharmacy Issues within a Retail Setting continued

- Brand Name vs. Generic Drugs
- Accuracy of reported National Drug Code
- Credit balances

Auditing Tips

- Cannot bill for more expensive and dispense cheaper medication
- Ensuring the correctly reported NDC is what is actually being dispensed

Hospital Provider-Specific Issues

Pharmacy Issues within a Hospital Setting

- Overall systems billing – APC unit conversion
- Brand Name Billing vs. Generic Billing

Auditing Tips

- Overall review of medication set-up
- Patient's bill tells the story

Hospital Outpatient Departments

- To bundle or unbundle, that is the question
 - Integral to procedure
 - Costs need to be reported

Auditing Tips

- Development of P&P to support charging structure
- Future Medicare reimbursement

Hospital Outpatient Departments

- Self-administrable
 - Chemotherapy session
 - Eye cases
 - Emergency Departments

Auditing Tips

- System can support regulation
- Ensuring that charging can support actual use of product
- Oral and identified medication

Medicare and Medicaid

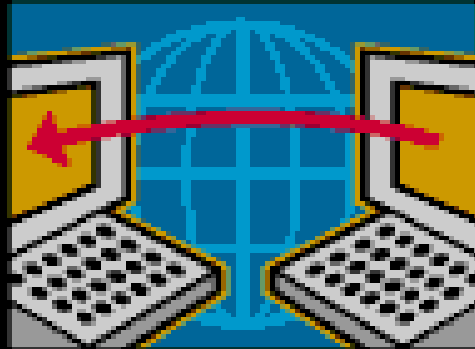
- Keeping it straight - Part A vs. Part B vs. Part D
- Self-administered medications

Auditing Tips

- Where is the medication administered
- Understanding the differences

Review of Billing Systems

- Use of multiple systems
- If gone unchecked, could be a major barrier to billing compliance



Automated Dispensing Systems (e.g. Pyxis)

- Checks and balances
- Multiple doses being charged
- Medications dispensed in different departments



Auditing Tips

- Does the system charge directly
- Monitoring set-up for accuracy
- Billing units vs. dispensing units
- Charging within institution should be same

Risk Assessment

Integrate Pharmacy Issues into Risk Assessment

- Assessment
 - Industry guidance
 - Audits (internal or external)
 - Interview key business leads
 - Field personnel – outside
 - Consideration of conducting interviews under Attorney-Client Privilege
 - Compliance can be anything

Evaluation

- Expanded scope of “compliance”
- Include others outside of areas
- Immediate issue – stop billing
- When to involve legal advisement

Prioritization

- System-wide initiatives
- Overall review and ranking of issues
- Compliance Committee
- Ranking top of list

Implementation

- Demonstration
- Risk of not addressing
- Monitoring
- Scorecard

Additional Areas for Pharmacy Compliance Review

Clinic Based Medication Billing

- Regularly review reimbursement rates
- Documentation requirements
- Off-label Use

Auditing Tips

Monitor is preauthorization is required

Diagnosis codes correctly coded

Issues Which Could Be a Result of Non-Compliance

- Safety and quality concerns
 - Organizational polices
- Reporting systems
 - Adverse drug
- Education, enforcement and monitoring

Specialty Business Operations

- Ambulance services
- Durable medical equipment
- Hospice
- Home care
- Mail order

Auditing Tips

Medications are set up, stored, prepared, dispensed and administered in many businesses – ensuring documentation is available to support any administration

Educate, Educate, Educate

- Provider documentation
- Correctly crediting & wasting of medications
- Quality assurance measures

Compliance in 2007

Impact of the Ever-Changing Regulations

- Process to continually assess regulations
- Newly approved medications
- Capturing the correct reimbursement
- Charge Master coding
 - Ensuring proper codes are being submitted
- Educate on the ever-changing regulation
 - DRA
 - Billing correctly
 - Refill order

Risks on the Radar

- Requirements for the Deficit Reduction Act
 - Increase enforcement
 - Whistleblower protection
 - CMS/Medicaid Integrity Program
- Medicare Part D

The "Other" Regulators

- DEA
- OSHA
- JCAHO
- FDA
- State Board Associations

Controlled Medications

Review Controls for Overall Drug Safekeeping

- Verify that the pharmacy segregates controlled drugs in a locked room (or drawer) and properly adds these to controlled substance logs as required by the U.S. Drug Enforcement Agency
- Review the procedures for counting and safekeeping controlled drugs
- Ask the pharmacy whether it performs occasional counts of non-narcotic drugs to verify the accuracy of the perpetual inventory

Medication Controls

- Review procedures for stocking shelves with the drugs
- Make sure the pharmacy properly labels shelves and includes sufficient space for storage

Controlled Medications

- Record keeping
 - Readily available
- Segregation of duties
 - Inventory controls
- Controls within site
 - Restrict access
- Power of Attorney documentation
- Report of theft

Retention of Documents

- State vs. Federal rules
- Ever changing requirements
- Hospital vs. Retail

Pharmacy Compliance Program

- Assessing the effectiveness and efficiencies through monitoring
- Implementation of P&P
- Identification of process improvement opportunities
- Corrective action plans

Questions



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Reference

Listing of Acronyms

- ASP Average Sales Price
- CIA Corporate Integrity Agreement
- CAP Competitive Acquisition Program
- DEA Drug Enforcement Administration
- AWP Average Wholesale Price
- OSHA Occupational Safety Health Administration
- DRA Deficit Reduction Act
- APC Ambulatory Payment Classifications
- HCPCS Health
- JCAHO Joint Commission on Accreditation of Healthcare Organizations