Pharmacy Compliance - Credentialing, HIPAA and Fraud, Waste and Abuse (FWA)

ACPE# 0761-9999-16-075-L04-P
ACPE# 0761-9999-16-075-L04-T
Credentialing and Other Terms the Pharmacy Should Know
What are all these terms and acronyms?

- **Credentialing** - the process of establishing the qualifications of licensed professionals, facilities or organizations, and assessing their background and legitimacy.
- **HIPAA** - Health Insurance Portability and Accountability Act (law protecting personal health information)
- **FWA** - Fraud, Waste and Abuse
- **Compliance** - conformity in fulfilling official requirements
Compliance Requirements

- OIG/GSA Reviews
- FWA Training
- Compliance / Code of Conduct Training
- HIPAA Training
- Records Retention
- CMS 10147
- Pseudoephedrine Training
- Drug Supply Chain Security
- Quality Assurance Program/ Error Reporting
- Current Licensure: State, Pharmacist (PIC), DEA, Certificate of Insurance, etc.
Effective Compliance Program

Elements of an Effective Compliance Program:
1. Leadership, Accountability & Structure
2. Written Standards
3. Education & Training
4. Auditing & Monitoring
5. Reporting
6. Enforcement & Discipline
7. Response & Prevention
Health Insurance Portability and Accountability Act (HIPAA)
Privacy Rule (164.5xx)

• Went into effect in April of 2003.
• Addresses how you may use and disclose Protected Health Information (PHI)
• Provides the patient with specific rights when it comes to their PHI
• Requires the designation of a Privacy Official (Officer)
<table>
<thead>
<tr>
<th>Individual’s Rights</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notice of Privacy Practices</td>
</tr>
<tr>
<td>Access to Records</td>
</tr>
<tr>
<td>Amendment of Records</td>
</tr>
<tr>
<td>Accounting of Disclosures</td>
</tr>
<tr>
<td>Confidential Communications</td>
</tr>
<tr>
<td>Additional Restrictions</td>
</tr>
</tbody>
</table>
Patients Rights

• Patient has the right to amend their records if they believe their records are incorrect or incomplete.
• Patient can request that you communicate with them in alternate means or locations.
• Patient can request additional restrictions be made to the uses and disclosures of their PHI.
• Omnibus specified that a patient could request that you do not release PHI to payers for services paid out-of-pocket
Definitions

**Uses** means, with respect to individually Identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within the Pharmacy

**Disclosures** means the release, transfer, provision of access to, or divulging in any manner of information outside the entity holding the information.
# Uses and Disclosures

<table>
<thead>
<tr>
<th>Uses and Disclosures</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>For Treatment, Payment and Health Care Operations</td>
<td></td>
</tr>
<tr>
<td>That Require Authorizations</td>
<td></td>
</tr>
<tr>
<td>Requiring an Opportunity for the Patient to Agree or Object</td>
<td></td>
</tr>
<tr>
<td>Not Requiring an Opportunity for the Patient to Agree or Object</td>
<td></td>
</tr>
</tbody>
</table>
Minimum Necessary

All uses and disclosures must be comprised of the minimum amount of Protected Health Information necessary to meet the purpose of the use or disclosures.
Valid Authorizations

A Valid Authorization must have:

- Description of the PHI that will be used or disclosed
- Persons or entities that will be receiving the PHI
- Purpose of the use or disclosure
- Expiration date of the authorization
- Patient Signature and date signed
- Wording that the patient may revoke the authorization
Identity Verification

The Pharmacy must verify the identity of a person/entity requesting PHI and the authority of any such person to have access to PHI.
HIPAA Housekeeping

- Policies and Procedures
  - Must have policies and procedures to comply with the regulations
- Employee Sanctions
  - Must have a process to apply sanctions to an employee who violates your HIPAA Practices
- Record Retention
  - Must maintain records for at least 6 years
- Training
  - Must train your employees on your policies and procedures
  - If you purchased a training program that is not based on your policies and procedures then you are non-compliant.
HIPAA Housekeeping (cont.)

- Employee Access
  - You must evaluate and document each employee based on the level of access to PHI they need in order successfully perform their job function.

- Inventory of PHI
  - You need to identify all of the locations (Physical and Electronic) in your Pharmacy that contain PHI. Cannot protected what you do not know exists.

- Complaints
  - A process to address complaints concerning HIPAA compliance
A “business associate” is a person or entity that performs certain functions or activities that involve the use or disclosure of PHI on behalf of, or provides services to, a covered entity.
Examples of Business Associates

- Accounting Services
- Legal Services
- Computer Software Vendors
- Consulting Services
- Online Storage entities
- E-Prescribing Services
- Shredding Companies
- Medical Billers

Are they a Business Associate?

- Yes
  - They come in contact with or potentially come in contact with personal health information

- No
  - Their services do not cause them to have access to personal health information.
Breach Notification Rule (164.4xx)

Must report a breach unless there is a low probability that the protected health information has been compromised based on a risk assessment

- Notify the affected individual(s) within 60 days of discovery
- 500 or more persons affected, notify HHS within 60 days of discovery
- Less than 500 persons affected, notify HHS within 60 days of the end of the year
Security Rule (164.3xx)

• Went into effect in April of 2005
• Governs how to ensure the confidentiality, integrity and availability of Electronic PHI
• Requires the designation of a Security Officer (Officer) with an understanding of your Computers and Network
Physical Safeguards

- Facility Access Controls
- Workstation Use
- Workstation Security
- Device and Media Controls
Technical Safeguards

- Access Controls
- Audit Controls
- Integrity
- Person or Entity Authentication
- Transmission Security
<table>
<thead>
<tr>
<th>Administrative Safeguards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Security Management Process</td>
</tr>
<tr>
<td>Workforce Security</td>
</tr>
<tr>
<td>Information Access Management</td>
</tr>
<tr>
<td>Security Awareness and Training</td>
</tr>
<tr>
<td>Security Incident Procedure</td>
</tr>
<tr>
<td>Contingency Plan</td>
</tr>
<tr>
<td>Evaluation</td>
</tr>
</tbody>
</table>
Fraud, Waste, and Abuse (FWA)
Background

The overall purpose of the fraud, waste, and abuse requirement is to protect the federal government and Medicare Part D beneficiaries from fraudulent, wasteful and abusive schemes, risks and vulnerabilities through the prescription drug benefit.
Fraud is defined as making false statements or representations of material facts in order to obtain some benefit or payment for which no entitlement would otherwise exist.

Waste is typically described as the over-utilization or misuse of services. The act of waste is typically not criminal or intentional.

Abuse describes practices that, either directly or indirectly, result in unnecessary costs to the Medicare program.
Regulations

• All Sponsors are required to have a comprehensive plan to detect, correct and prevent fraud, waste and abuse according to the Medicare Modernization Act.

• While it may be common practice for Sponsors to enter into contracts with third parties to perform certain functions that would otherwise be the responsibility of the Sponsor, the Sponsor maintains ultimate responsibility for fulfilling the terms and conditions as set out in the contract with CMS.

• Whenever a Sponsor delegates any of its activities or responsibilities to any related entity, contractor, subcontractor or pharmacy, the written arrangements must either provide for revocation of the delegation activities or specify other remedies in instances when CMS or the Sponsor determine that the parties have not performed satisfactorily.
Plan Sponsor and PBM – Areas of Focus

- Daily Audit Programs
- Hospice, ESRD, COB
- Excluded Provider Exclusions
- Onsite Audits
- Corrective Action Programs
- Credentialing / Re-credentialing program
- FWA report creation/ review
- HEAT area reporting / investigative monitoring
- Investigation – including Invoice Auditing
- Medicare Drug Integrity Contractors (MEDIC) information sharing
- Law Enforcement / MEDIC referrals
Potential Fraud, Waste and Abuse schemes can be perpetrated by prescribers, members, and pharmacies:
Common attributes of fraudulent schemes:

- A significant increase in prescription orders and claim submissions from one physician and/or office
  - Prescriber’s will be difficult to contact and/or only the “front office nurse” or “office manager” will answer the phone or return calls upon verification attempts
  - The prescriber listed on the Rx may be new to the area and unfamiliar to the pharmacy
  - Physician Assistant’s writing for Rx’s without proper identification on prescriptions
  - Repetitive patterns may contain the same drug or drug class, strengths and dosing for each member and will be for single source brand name drugs only
  - In many cases, such prescriptions will be written for a 90-day supply
  - Member specifically requests sealed medication bottles
- Members traveling great distances to obtain their prescriptions at the pharmacy
- Frequent misspelled addresses, cities, names, and/or drugs
- Perfectly written or incorrect prescriptions with same script from different prescribers
Examples of Fraud, Waste and Abuse by prescribers to watch for:

- Illegal remuneration schemes – prescriber is offered, paid, solicits or receives unlawful remuneration to induce or reward the prescriber to write prescriptions (kick backs)
- Prescription drug switching – offers in cash or other benefit to prescribe one drug over another
- Script mills – writing prescriptions for drugs that are not medically necessary, often in mass quantities, and often for individuals that are not his or her patients
- Theft of prescriber’s Drug Enforcement Administration (DEA) number, Prescription pad, or e-prescribing authentication information and log-in
Examples of Fraud, Waste and Abuse by members to watch for:

• Over-utilization and drug seeking – drug abuse (not limited to narcotics)
• Altered and forged prescriptions – dates, strengths, quantities, refills, false claims
• Members initiating their own phone-in prescriptions
• Pharmacy hopping and doctor shopping – review history of member
• Drug diversion and inappropriate use – obtains drugs used by another non-covered party, or for resale on the black market
• Misrepresentation of status – member misrepresents identity, eligibility, medical conditions to obtain benefits
Examples of Fraud, Waste and Abuse by pharmacies to watch for:

- Billing for brand and dispensing generic drugs
- Over-billing of quantity prescribed and inappropriate billing of compounds
- Over-billing of quantity in relation to days’ supply / reducing qty to avoid p/a
- False or fictitious claims submission
- Document fabrications and alterations
- Forged signature logs or insufficient proof of delivery
- Not processing returns to stock / Not crediting for destroyed returns
- Use of dummy DEA’s/National Provider Identifier (NPI)
- Inappropriate use of Dispense As Written (DAW) codes
- Billing of unauthorized refills
- Billing under expired prescriptions
- Prescription splitting to obtain multiple dispensing fees
- Pill shorting – billing for more than dispensed
- Recycling medications – black market repurchases for resale
- Failure to offer negotiated prices
Elements of FWA programs

1. Written Policies and Procedures required by pharmacies
2. Exclusion Lists
3. Staff Training and Education
4. Conflict of Interest
Written Policies and Procedures

- Written policies, procedures, and standards of conduct clearly stating a Sponsor or Pharmacy’s commitment to comply with all applicable Federal and state statutory, regulatory and other requirements related to the Medicare program are a critical component of a comprehensive program to detect, prevent and control fraud, waste and abuse.
- The Code of Conduct and the applicable policies and procedures should be made available to employees at time of hire, when the standards are updated, and annually thereafter. As a condition of employment, employees should certify that they have received, read, and will comply with all written standards of conduct.
- Written policies, procedures and standards of conduct should be updated as necessary to incorporate any changes in applicable laws, regulations, and other requirements.
Exclusion Lists

Pharmacies contracted with Medicare D plan sponsors or their PBMs are required to comply with CMS requirements.

Screening of Employees – Employees should be checked against the OIG and GSA lists at time of hire and monthly thereafter to ensure that no employee is prohibited from participation in the Medicare program.
The Online Searchable Database enables users to enter the name of an individual or entity and determine whether they are currently excluded. If a name match is made, the database can verify the match using a Social Security Number or Employer Identification Number.

OIG - http://exclusions.oig.hhs.gov/

The Online Searchable Database enables users to enter the name of an individual or entity and determine whether they are currently excluded. If a name match is made, the database can verify the match using a Social Security Number or Employer Identification Number.
GSA – www.sam.gov

All entity records from CCR/FedReg and ORCA and exclusion records from EPLS, active or expired, were moved to SAM. You can search these records and new ones created in SAM.
Conflicts of interest are created when an activity or relationship renders a person unable or potentially unable to provide impartial assistance or advice, the person’s objectivity is impaired, or a person has an unfair competitive advantage.
Important Points to Remember

- The pharmacy has a legal and contractual duty to not submit false claims, including claims arising from the previous noted schemes;
- If the pharmacy has a significant increase in a particular prescriber’s prescriptions, pharmacy should directly contact such prescriber to determine legitimacy of such prescriptions; and
- Verify authenticity of members’ form of identification receiving prescriptions by asking the Member to confirm information on the identification they have provided
- Be cognizant of schemes involving patient recruiting schemes where identities are stolen
- Know your patient and their medical condition
- Be careful about engaging in the practice of pre-signed delivery authorizations
- Question medical practices channeling new business to your pharmacy
- If it sounds too good to be true or doesn’t seem right, it probably isn’t. Question it!
Reporting FWA

How can you report actual or suspected Fraud, Waste or Abuse?

– In most cases, an immediate supervisor may be in the best position to address issues.
– PBMs and Medicare Sponsor processors have a Hotline or reporting protocol.
– Reports of FWA or compliance are to be treated as “Confidential”
– Employees are protected from retaliation under the False Claims Act for False Claims Act complaints.
## Where Should I Report Fraud and Abuse?

<table>
<thead>
<tr>
<th>I am a...</th>
<th>Report to...</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medicare Beneficiary</strong></td>
<td>For any complaints:</td>
</tr>
<tr>
<td></td>
<td>CMS Hotline: 1-800-MEDICARE (1-800-633-4227) or TTY 1-800-486-2048 OR</td>
</tr>
<tr>
<td></td>
<td>For Medicare Managed Care or Prescription Drugs: 1-877-7SafeRx (1-877-772-3379)</td>
</tr>
<tr>
<td><strong>Medicare Provider</strong></td>
<td>OIG Hotline</td>
</tr>
<tr>
<td></td>
<td>Phone: 1-800-HHS-TIPS (1-800-447-8477)</td>
</tr>
<tr>
<td></td>
<td>Fax: 1-800-223-8164</td>
</tr>
<tr>
<td></td>
<td>E-mail: <a href="mailto:HHSTips@oig.hhs.gov">HHSTips@oig.hhs.gov</a></td>
</tr>
<tr>
<td></td>
<td>TTY: 1-800-377-4950</td>
</tr>
<tr>
<td></td>
<td>Mail: US Department of Health and Human Services Office of Inspector General Attn: OIG Hotline Operations P.O. Box 23489 Washington, DC 20026</td>
</tr>
<tr>
<td></td>
<td>OR your local Medicare Carrier, FFS, or MAC</td>
</tr>
<tr>
<td><strong>Medicaid Beneficiary or Provider</strong></td>
<td>OIG Hotline</td>
</tr>
<tr>
<td></td>
<td>Phone: 1-800-HHS-TIPS (1-800-447-8477)</td>
</tr>
<tr>
<td></td>
<td>Fax: 1-800-223-8164</td>
</tr>
<tr>
<td></td>
<td>E-mail: <a href="mailto:HHSTips@oig.hhs.gov">HHSTips@oig.hhs.gov</a></td>
</tr>
<tr>
<td></td>
<td>TTY: 1-800-377-4950</td>
</tr>
<tr>
<td></td>
<td>Mail: US Department of Health and Human Services Office of Inspector General Attn: OIG Hotline Operations P.O. Box 23489 Washington, DC 20026</td>
</tr>
<tr>
<td></td>
<td>OR your Medicaid State Agency (State Agency Fraud Units are listed at <a href="http://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/FraudAbuseforConsumers">http://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/FraudAbuseforConsumers</a>)</td>
</tr>
</tbody>
</table>
Penalties of Violating FWA

- Network Termination
- Payment Suspension
- Suspension of Enrollment and Marketing Activity – Plan Sponsors
- Civil Monetary Penalties
  - Under 42 U.S.C. Section 1320a-7a, CMPs may be imposed for a variety of conduct, and different amounts of penalties and assessments may be authorized based on the type of violation at issue. **Penalties range from up to $10,000 to $50,000 per violation.** CMPs can also include an assessment of up to 3 times the amount claimed for each item or service, or up to 3 times the amount of remuneration offered, paid, solicited, or received.

Examples of CMP violations include:
- Presenting a claim that the person knows or should know is for an item or service that was not provided as claimed or is false and fraudulent,
- Presenting a claim that the person knows or should know is for an item or service for which payment may not be made, and
- Violating the Anti-Kickback Statute.