



# pharmacy & 2011 technology conference

August 27 - 30, 2011 ■ Boston Convention & Exhibition Center ■ Boston, MA

**Date:** Sunday, August 28, 2011

**Time:** 9:45 a.m. – 10:45 a.m.

**Location:** Boston Convention & Exhibition Center, Meeting Level 2, Room 257 AB

**Title:** **Fraud Waste and Abuse Update**  
ACPE # 0206-0000-11-508-LO3-P (0.1 CEU)

**Speaker:** Don L. Bell, II, JD, National Association of Chain Drug Stores

---

## **Learning Objectives:**

At the conclusion of this knowledge-based program, participants will be better able to:

- Explain new fraud and abuse requirements established by the health care reform law
- List fraud and abuse standards applicable to pharmacies
- Identify steps companies can take to prepare for audits and investigations from agencies and contractors

Don't forget to obtain continuing education credit for your participation in this session. Instructions for processing your statement of credit online are included in your registration bag.

# FRAUD AND ABUSE UPDATE

**Don L. Bell, II**  
Senior Vice President & General Counsel  
National Association of Chain Drug Stores  
(703) 837-4231 DBell@NACDS.org

## Agenda

- **Update On Implementation Of New Laws**
  - New rules and guidance
- **New Enforcement Trends**
- **Audits And Provider Screening**
- **Crime And Punishment**
  - Fraud and Exclusions
- **Compliance Requirements And Tips**

## Growing Enforcement

## 2010 Health Reform Law

- **Increased Enforcement Funding**
- **More Investigations And Audits**
- **New Provider Requirements**
- **Stronger Standards For Fraud, Kickbacks**
- **Greater Penalties And Exclusions**

## 2010: Growing Enforcement

- **\$4+ Billion Recovered By HCFA**
  - \$3 Billion in 2009
- **5,072 Under Criminal Investigation**
  - 4,492 in 2009
- **2,232 Civil Fraud Investigations**
  - 2,041 in 2009
- **3,340 Excluded From Medicare/Medicaid**
  - 2,556 in 2009

Source: Health Care Fraud & Abuse Control Program Annual Reports (2009 & 2010)

## Enforcement Growth Continues

- **Record Monetary Recoveries**
  - OIG alone projects \$3.4 billion recovered from audits and penalties in 1<sup>st</sup> half of FY 2011
- **Aggressive Exclusions Continue**
  - OIG excluded 883 companies and individuals from Medicare and Medicaid in 1<sup>st</sup> half of year
- **2012: Another Record Year?**
  - Administration proposes to increase HCFA funding to \$1.9 billion (from \$1.4 billion in 2011)

Source: OIG Semiannual Report To Congress (June 2011)

## Enforcement Programs

- **Many Different Programs**
  - Example: Senior Medicare Patrol
- **New Risk Scoring Technology**
  - Software to predict who will bill inappropriately
- **Center For Program Integrity**
  - New CMS priority center is up and running



## Reasons For Increased Enforcement

1. **More Health Spending**
2. **Deficit Pressure**
3. **Enforcement Is Profitable**
  - 898% return on investment!
  - Bounty hunters find free money
4. **Horror Stories**



**STOP Medicare Fraud**  
U.S. Department of Health & Human Services and U.S. Department of Justice

pharmacy     Results 1 - 10 of about 63 for pharmacy. Search took 0.11 seconds. Sort by date / Sort by relevance

**Search**  
 Ritten was a pharmacist and the prior owner of Ritten's Pharmacy, while George Devine was employed as a pharmacy technician at...  
[www.stopmedicarefraud.gov/EA7news/kyntucky.html - 27k - 2011-07-26](#)

**News Type**  
 Pharmadom was the name of two Manhattan pharmacies known as A & S Pharmacy and S&S Pharmacy which are no longer in business...  
[www.stopmedicarefraud.gov/EA7news/nyc\\_york.html - 50k - 2011-07-26](#)  
[\[More results from www.stopmedicarefraud.gov/EA7news/\]](#)

**IPPI Blue Health Care Fraud Consumer Aid Sheet**  
 ... Also, the copies of all bills or notices from insurance companies, doctors, hospitals, pharmacies, etc., so well as canceled checks...  
[www.stopmedicarefraud.gov/pressreleases/amp/documents/consumer\\_aidsheet.pdf - 2011-07-11](#)  
[www.stopmedicarefraud.gov/EA7news/georgia - 48k - 2011-07-07](#)

**Scotist**  
 indictment alleges that the insurer failed to provide these services, in part by failing to use General Power and orders of pharmacy and device...  
[www.stopmedicarefraud.gov/EA7news/georgia - 48k - 2011-07-07](#)

**2010 Florida News Notes**  
 ... defendant and his co-defendant were the true owners of four separate pharmacies that submitted false claims to Medicare...  
[www.stopmedicarefraud.gov/EA7news/florida/fact010 - 131k - 2010-12-17](#)

**2010 California News Notes**  
 ... In Connection With False Agency Pharmacy Investigation (US Attorney's Office, the Northern District of California), Online Pharmacies Targeted...  
[www.stopmedicarefraud.gov/EA7news/california/calact010 - 92k - 2010-11-23](#)

**News**  
 ... Medicaid is a Federal Health Care Program, reimbursed the clinic for visits that were not medically necessary and the pharmacy for prescriptions to...  
[www.stopmedicarefraud.gov/EA7news/illinois/illnews.html - 56k - 2010-10-06](#)

**HEAT Task Force Meets**  
 ... Heat Task Force, July 29 2010 - Former Pharmacy Technician  
 Health Care is Health Care Fraud - Heat News, LLC...  
[www.stopmedicarefraud.gov/news - 23k - 2010-07-29](#)

**Tejas**  
 Pharmacy Services, Inc. And Quantum Infusion, Inc. and was a director of Texas Home Infusion, LLC. She admitted that three pharmacists were...  
[www.stopmedicarefraud.gov/news/tejas.html - 101k - 2010-07-29](#)  
[http://www.stopmedicarefraud.gov/news](#)

**2009 Texas News Notes**  
 Pharmacy Services, Inc. And Quantum Infusion, Inc. and was a director of Texas Home Infusion, LLC. She admitted that three pharmacists were...  
[www.stopmedicarefraud.gov/EA7news/tejas/2009fact.html - 77k - 2009-12-21](#)  
[www.stopmedicarefraud.gov/EA7news/tejas/2009fact.html - 77k - 2009-12-21](#)

Result Page 1 2 3 4 5 6 7 Next

U.S. Department of Health & Human Services  
**Office of Inspector General**  
U.S. Department of Health & Human Services

pharmacy

About OIG Reports & Publications Fraud Compliance Recovery Act Oversight Exclusions Newsrooms

Home > Search  
 Search for "pharmacy"    Results 1 - 10 of about 63 for pharmacy. Search took 0.04 seconds. Sort by date / Sort by relevance

**IPPI Medicare Part D Pharmacy Discounts for 2009 (OCI) 02-20**  
 ... Sponsors also contract with PBM's to negotiate discounts with pharmacies. These pharmacy discounts affect the price that beneficiaries and the...  
[og.hhs.gov/pressreleases/02-10-091020.pdf - 2009-12-01](#)

**IPPI Medicaid Pharmacy Discounts, LLC (M) 03-08-09**  
 ... consistent with Maryland State Board of Pharmacy requirements and any other Federal or state law governing the operations of pharmacies...  
[og.hhs.gov/medicaidagreements/mo/medicaid\\_pharmacy\\_services\\_llc\\_03a\\_remed\\_services.pdf - 2010-12-20](#)

**IPPI F. FRISVOLD, NIGEL R. BOTSCH, R PH AND PHARMACY L.V. ASSOCIATES OF DEXTER, CT, INC. - Pharmacy L.V. Associates of Dexter, Inc. (DAR) -**  
[og.hhs.gov/medicaidagreements/pharmacy\\_lv\\_associates\\_08112009.pdf - 2009-09-03](#)

**IPPI F. FRISVOLD, FRISVOLD Alan D. Kohal, Kohal Pharmacy, Inc. and Kohal Pharmacy and Medical Supply, Inc. - Kohal Pharmacy Corporate Integrity Agreement -**  
[og.hhs.gov/medicaidagreements/kohal\\_pharmacy\\_inc\\_0812007.pdf - 2007-07-03](#)

**IPPI Medicaid Recovery of Pharmacy Payments from Liable Third Parties**  
 ... Medicaid agencies with a cost-avoidance waiver for pharmacy services may reimburse pharmacies that serve beneficiaries who have other...  
[og.hhs.gov/pressreleases/03-06-090303.pdf - 2001-08-01](#)

**IPPI Evaluation of Health Maintenance Organizations with**  
 ... On the pharmacy network contracts with individual community-based pharmacies to form a network of providers participating in the health plan...  
[og.hhs.gov/pressreleases/01-06-091010.pdf - 1997-04-01](#)

**IPPI Retail Pharmacy Participation in Medicare Part D Prescription**  
 ... Under Part D, plans contract with pharmacies to insure pharmacy networks that provide Part D covered drugs to beneficiaries enrolled in...  
[og.hhs.gov/pressreleases/05-06-090503.pdf - 2007-06-01](#)

**HS/OCG-Audit - Pharmacy Health Professions Student Loans**  
 ... Pharmacy Health Professions Student Loans Program at the Massachusetts College of Pharmacy, Boston, Massachusetts. (4-05-09-0004)

**I'm looking for**  
 Let's start by choosing a topic:

- What's New
- News Releases
- Podcasts
- Testimony & Speeches
- Video

**EXCLUSIONS DATABASE**

**REPORT FRAUD**

**OIG/HHS on Twitter**

**Get Email Updates**  
 Sign up to see on the latest OIG news and updates.

NACADS NATIONAL ASSOCIATION OF COMMUNITY AND CLINICAL PHARMACEUTICAL DISTRIBUTORS

**Audits**

Pharmacies. The face of neighborhood healthcare.

NACADS NATIONAL ASSOCIATION OF COMMUNITY AND CLINICAL PHARMACEUTICAL DISTRIBUTORS

**Government Audits**

- **CMS Access To Pharmacy Records**
  - New Medicare rule says CMS can “audit, evaluate and inspect any” pharmacy records
- **More Data Mining By Law Enforcement**
  - Starting “Integrated Data Repository”
  - OIG proposes to expand data mining by states
- **But Audit Tactics Not Unlimited**
  - See Rite Aid of New York decision

Pharmacies. The face of neighborhood healthcare.

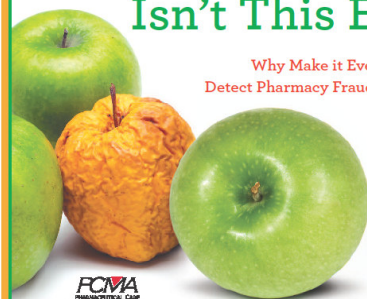
### RAC Audits

- **Recovery Audit Contractors (RACs)**
  - Bounty hunters paid based on how much they recoup
  - Use extrapolation audits
- **CMS Hired Medicare Part D RAC**
  - Will review Part D plan compliance programs
    - Including review of pharmacy claims
- **Medicaid RACs Are Coming**
  - States must hire RACs
  - CMS proposed rule gives states flexibility

### Plan/PBM Audits

- **Medicare Part D Plans Implementing Mandatory Fraud Programs**
  - CMS guide calls for extremely thorough audits
  - New CMS rule says Medicare plans must disclose “any” records from pharmacies
- **New Legislation Limiting PBM Audits**
  - New laws in AK, NC, ND, OK and federal bills
- **PCMA Response:**  
**“The Drugstore Lobby vs. Employers”**

## Spotting Bad Apples Isn't This Easy...



Why Make it Even Harder to  
Detect Pharmacy Fraud, Waste, & Abuse?

Health care fraud, waste,  
and abuse costs Americans  
up to \$234 billion a year.

Why does the  
Independent Drugstore  
Lobby want to make it even  
harder to detect?



Oppose H.R. 1971/S. 1058  
[Click Here to Learn More](#)

## Provider Screening

### Increased Screening

- **New CMS Screening Rule**
  - Can include background checks, licensure reviews, fingerprinting, database searches, inspections, etc.
  - Screening varies based on risk level
  - Medicare: New Part B suppliers are “high risk”
  - Medicaid: States will decide if pharmacies are “high,” “medium” or “low” risk
- **CMS And States Can Freeze Enrollment**
  - Specific locations or types of providers/suppliers
  - Will freeze if identify fraud “trend”

### DMEPOS Standards

- **New CMS Rule Imposes Strict Requirements**
- **Bans Subcontracting Out Most Services**
  - In April CMS proposed relaxing this requirement
- **No Contacting Patients w/o Their Permission**
  - April proposal would limit the ban to telemarketing
- **Other Requirements**
  - Requires landline phone, minimum office size, visible signs, minimum hours, inspections, bans sharing space

### Crime

### Federal False Claims Act

- **The False Claims Act Prohibits Knowingly:**
  - Presenting false claim for payment to government
  - Making or using false record or statement to get claim paid by government
  - Conspiring to get false claim paid by government
  - Using false record to avoid paying government

### False Claims Examples

- **Submit Claims For Drugs Not Dispensed**
  - Forged, altered or “purchased” prescriptions
- **Double Billing**
  - Multiple claims to payor(s) for same Rx
- **“Shorting” Or Partial Fill**
  - Partially fill vial but charge for full prescription
  - No arrangements for patient to pick up remainder
  - If not picked up, may need to reverse part of claim
- **Dispense Generic, Bill For Brand**
  - Pharmacist writes “dispense as written” on Rx

### State False Claims Acts

- **OIG Reviews State False Claims Acts**
  - Federal law gives more Medicaid \$\$ to states with stronger false claims laws
- **OIG Looks For:**
  - Liability for same fraud as federal law
  - Penalties at least as strong as federal law
  - Encouragement of whistleblowers
- **OIG Recently Rejected 24 State Laws**
  - Expect the states to strengthen their false claims laws

### Overpayments As False Claims

- **Fraud Enforcement And Recovery Act**
  - Knowingly keeping overpayment by Medicare or Medicaid violates False Claims Act
  - Even if you never submitted a false claim
- **Health Reform Law (PPACA)**
  - Must return overpayment within 60 days of discovery
    - Also “explain in writing the reason for the overpayment”
  - Penalties if fail to repay: \$10k fine per overpayment plus 3 times actual damages

### Anti-Kickback Laws

- **Anti-Kickback Laws**
  - Illegal to pay for referral of patient covered by Medicare, Medicaid or other government program
  - Federal and state laws
- **Examples**
  - Pharmacist pays physician for referred patient
  - Pharmacist pays patients for submitting Rx's
  - Pharmacist paid for each patient “steered” to Part D plan

## Waivers For ACOs

- **Accountable Care Organizations**
  - Encouraged by the health reform law
  - Different providers will share savings and risk by being jointly responsible for patient care
  - Designed to reduce overall costs
- **Waiver Of Anti-Kickback Law Needed**
  - ACOs necessarily involve rewarding referrals among providers
  - OIG and CMS have proposed weak waivers

## Punishment

## Reimbursement Suspension

- **New CMS Rule And Bulletin**
- **If “Credible Allegation Of Fraud” ...**
  - With “indicia of reliability” (e.g., “hotline complaint”)
- **Then During Investigation ...**
  - CMS can halt Medicare reimbursement
  - States must halt Medicaid reimbursement
- **Exceptions**
  - “Good cause”
  - “Mere errors” (e.g., unintentional “human errors”)

## Program Exclusion

- **Individuals & Companies Can Be Banned**
  - From Medicare, Medicaid, other programs
  - Reasons for exclusion include:
    - Violate fraud and abuse laws
    - Board actions (e.g., BoP revokes license)
    - Controlled substances violations
    - Default on federal student loans, crimes, etc.
- **Pharmacy Liable For Excluded Employee**
  - If involved “in any way” with filling or billing Rx
  - Penalties: recoupment + \$10k fine/Rx + 3x damages

## Program Exclusions

- **Additional Medicaid Exclusion**
  - State must exclude if excluded from Medicare or other state's Medicaid program
- **Exclusion For Obstructing Audit**
  - Also fined \$15k per day if fail to give OIG "timely" access during audit or investigation
- **Exclusion For False Statements**
  - In provider agreements or enrollment forms
    - Even if no false claim for payment
  - Also \$50k fine plus 3 times actual damages

## New Emphasis On Executives

- **OIG Guidance On Executives And Owners**
  - Beyond exclusion of company
  - "Rebuttable presumption" of exclusion if executive "knew or should have known" of improper conduct
  - OIG considers executive's role in company, response to misconduct, seriousness of the offense, etc.
- **Several Recent Drug Industry Examples**
  - Federal court recently affirmed exclusion of CEO, head scientist and head lawyer of drug manufacturer
  - Excluded 12 years, fined \$35+ million, probation, etc.

U.S. Department of Health & Human Services  
Office of Inspector General

This Web page contains information about OIG's most-wanted health care fugitives. In all, we are seeking more than 170 fugitives on charges related to health care fraud and abuse.

 <b>Carlos Barrios</b> DOB: 08-23-1961 Height: 5'6" Weight: 160 lbs. WANTED	 <b>Luis Barrios</b> DOB: 05-09-1966 Height: 5'11" Weight: 160 lbs. WANTED
 <b>Jose Barrios</b> DOB: 08-29-1954 Height: 5'11" Weight: 162 lbs. WANTED	 <b>Dr. Steven Moss</b> DOB: 01-22-1959 Height: 6'2" Weight: 160 lbs. WANTED
 <b>Caridad Sultano</b> DOB: 02-28-1967 Height: 5'7" Weight: 144 lbs. WANTED	 <b>Reynold Rotencourt</b> DOB: 01-09-1959 Height: 5'11" Weight: 144 lbs. CAPTURED
 <b>Chris Roberts</b> DOB: 04-22-1964 Height: 5'7" Weight: 144 lbs. WANTED	 <b>Brian Sledge</b> DOB: 03-29-1979 Height: 6'4" Weight: 130 lbs. WANTED
 <b>Edward Healy</b> DOB: 11-04-1965 Height: 5' Weight: 165 lbs. WANTED	 <b>Edward Moran</b> DOB: 05-19-1959 Height: 5'8" Weight: 160 lbs. WANTED

REPORT A FUGITIVE

Report Fraud | Accessibility | Privacy Notice | Disclaimer | Site Map  
 What's New | E-Mail List | Contact | Exclusion Database | Guidance Practices  
 HHS.gov | 1-800-368-1011 | OIG.gov | Other Agency Inspectors General

## Compliance

## Compliance Programs

- **Required For Medicare, Medicaid, CHIP**
  - OIG rule will identify content for particular industries
- **OIG's Elements Of Compliance Programs**
  1. Written policies and procedures
  2. Compliance officer and committee
  3. Employee training and education
  4. Method to report problems confidentially
  5. Routine internal monitoring and auditing
  6. Promptly respond to problems with corrective action
  7. Enforcement through disciplinary standards

## Compliance Programs

- **Required By Some Part D Plans Already**
- **Helps Limit Liability**
  - Shows actions of rogue individuals rather than company-wide failure
  - Lack of effective compliance program may be "reckless disregard" under False Claims Act
- **NACDS Model Compliance Program Manual**
  - 50+ pages of model language to start a program

## Training

- **CMS Rule Requires Annual Training**
  - For Medicare drug plans and providers
  - "All" employees must be trained?
- **But New Exception Currently In Place**
  - Pharmacy training not mandatory if DMEPOS accredited or otherwise enrolled in Part B
- **Plans Require Training**
  - CMS suggests Part D plans should require
    - Recommends "specialized" pharmacist training
    - When hired, annually, and if problems occur

## Training

- **OIG Report On Part D Training (July 2011)**
  - 87% of pharmacies said staff received training
  - Pharmacy training generally followed guidance
    - But "more than half of the materials were developed by pharmacies' corporate offices, despite CMS guidance ... that pharmacies should not develop their own materials"
    - And pharmacies did not include HIPAA in training
  - 70% of Part D plans said they require pharmacies to document training
  - OIG says CMS should review pharmacy training materials and should monitor training closely

### Training Sources

- **CMS May Require Plans To Provide Training Materials To Pharmacies**
  - OIG recommends in July report
  - But raises old issue of multiple training
- **CMS Will Provide Training Materials**
  - For pharmacies or just for plans?
- **“HEAT” Training On OIG Website**
  - Extensive, but not geared to pharmacies
- **NACDS Foundation And LearnSomething**
  - 20,000 pharmacies used

### Coupons And Rewards Programs

- **“Beneficiary Inducements” Law**
  - Prohibits payments and discounts to entice Medicare or Medicaid patients to use particular provider or product
  - Many chains carve out government programs
- **New Exception For Coupons And Rewards IF**
  - Offered by “retailer” on equal terms to general public, AND
  - Not “tied” to provision of “other” covered items or services
- **Other New Exceptions**
  - Benefits that promote access to care
  - Waive copays based on financial need or generic first fill
- **Be Careful: Still Awaiting OIG Guidance**

### More Compliance Tips

- **Monitor Exclusions List**
  - CMS says review “at least” annually and when hire
  - Some network contracts require regular searches
- **Review CMS Fraud And Abuse Guidance**
  - Many examples of pharmacy fraud and compliance
  - [www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBManual\\_Chapter9\\_FWA.pdf](http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBManual_Chapter9_FWA.pdf)
  - Summary available from me

## Thank You!

**Don L. Bell, II**  
 Senior Vice President & General Counsel  
 National Association of Chain Drug Stores  
 (703) 837-4231      DBell@NACDS.org