Compound Pharmacy Prosecutions: Past Lessons and Future Trends

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The Compound Drug Scheme

• Compounded Medicine: Allegedly Custom Tailored to Unique Health Needs of Individual Patients

• Targeted TRICARE and Government Retirement Programs

  • In the first 9 months of 2015, Tricare paid $1.7 billion, or 20% of their total prescription drug budget, on compounded drugs.

  • Compared to just $23 million in 2010, a 7,291% increase

  • In two years, TRICARE’s average cost for a compound drug jumped from $192 to $2,595

• Pain creams, scar creams, wound creams, hormone replacement

• Some egregious cases have involved compounded drugs ranging from $5,000 to $40,000 per script

• Defense Health Agency had to Seek Additional Funding to Cover $2 Billion Budget Hole

• Intense Media Scrutiny - CBS Nightly News and Wall Street Journal

• DOJ, DOD, OPM dedicate substantial resources to “clean up”
Compounding Pharmacy Fraud: Fact Patterns & Trends

- Physician Kickback Schemes:
  - Research Studies
  - Medical Director Positions
  - Providing High Salary Jobs to Spouses, Family Members
  - “Evaluation” or “Encounter” Fees for TeleMed Docs

- Marketer Kickback Schemes
  - % Based Compensation to Marketer; Commissions as High as $8,000 per script
  - Concealed as Hourly Fees for Lead Generation, Consulting, Patient Screening, Patient Verification

Compounding Pharmacy Fraud: Fact Patterns & Trends

- Patient Kickback Schemes:
  - Co-Pay Assistance
  - Research Participation Fees
  - % Payments and Untraceable Gift Cards

- Other Schemes
  - Identity Theft: Unsolicited Deliveries to TRICARE Beneficiaries
  - Targeted Phone Solicitations, Phishing Schemes
  - Doctors and Patients in Different States; No Physician Evaluation = No Bona Fide Patient-Physician Relationship
  - Changing Formulas to Maximize Reimbursement
Data Mining & Target Selection

• Historically, civil enforcement actions generated by whistleblowers
• Now, TRICARE Data Mining is Used to Identify Targets
• Data Doesn’t Lie; Signs of Trouble:
  • Rapid billing spikes for compounds drugs from 2013 to May 2015
  • Claims Attributable to a Small Number of High Volume Prescribing Physicians
  • Doctors and Patients in Different States
  • Multiple Compounds for Each Patient
  • Identical Compounds for Each Patient

Government Enforcement Tools

• Civil Enforcement Proceedings: False Claims Act
• Criminal Enforcements: Indictment in Florida, Texas, California
  • Prosecutors using traditional tools including search warrants, phone recordings, body recorders and surveillance.
• Administrative Sanctions
  • Exclusion Proceedings
  • Recoupmcnt of Overpayment
  • Corporate Integrity Agreements
• Other Remedies

Other Consequences

• State Licensure & Disciplinary Issues for Medical and Pharmacy Professionals
• Loss of Privileges at Hospitals
• Adverse Employment Actions
• Loss of Professional Opportunities
• Termination of Payor Contracts
• On-Site Inspections and Audits
• Public Shaming
TRICARE Rules:  
What You May Not Know

- Reimbursements Come from Private PBMs: Express Scripts and CVS Caremark.  
  - Don't be fooled; it is still government money
- Stark Law Not Applicable
- 60 Day Report and Refund Not Applicable
- Administrative Definitions (32 CFR 199.9)

Advice of Counsel Defense

- Very common in compounding pharmacy cases
- Many pharmacies sought legal advice regarding physician relationships and marketing relationships
- Gut-Wrenching Decisions for the Defense  
  - Waiving Privilege  
  - Exposing Advice, Good and Bad, to the Government  
  - Exposing Attorneys to Interviews  
  - Did your client tell attorney **everything**?  
  - Did the client really follow the advice?
- Possible malpractice claims against Attorneys

The Yates Memo:  
A Check May Not Solve the Problem

- To be eligible for any cooperation credit, corporations must provide to the Department all relevant facts about the **individuals** involved in corporate misconduct.
- Both criminal and civil corporate investigations should **focus on individuals** from the inception of the investigation.
- Criminal and civil attorneys handling corporate investigations should be in routine communication with one another. Every whistleblower case is evaluated by criminal.
- Absent extraordinary circumstances, no corporate resolution will provide protection from criminal or civil liability for any individuals.
- Corporate cases should not be resolved without a clear plan to resolve related individual cases before the statute of limitations expires.
- Civil attorneys should consistently focus on individuals as well as the company. Focus is on accountability and deterrent, not just money.
Compliance for Compound Pharmacies & Lessons Learned

- Hire a Compliance Officer
- Develop and Implement an Effective Compliance Program
- Conduct internal and coordinate external billing audits
- Develop and implement corrective action plans
- Train staff and providers to address compliance issues

What’s Next? Future Enforcement Trends

- Continued prosecutions – both civilly and criminally
- Expanded focus nationally
- Focus on pharmacies, doctors, marketers and others
- Other agencies getting involved
- Emerging growth of Department of Defense fraud investigators

Questions?