Compound Pharmacy Prosecutions: Past Lessons and Future Trends

March 29, 2017
National Harbor, MD

Health Care Compliance Association
21st Annual Compliance Institute

Elizabeth D. Shaw
RezLegal, LLC
Jacksonville, FL

Jason Mehta
Assistant U.S. Attorney
Jacksonville, FL

Ryan Stumphauzer
Stumphauzer & Sloman
Miami, FL

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
The Compound Drug Scheme

- 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
  - Recoupment 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 deterrence, 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?