

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

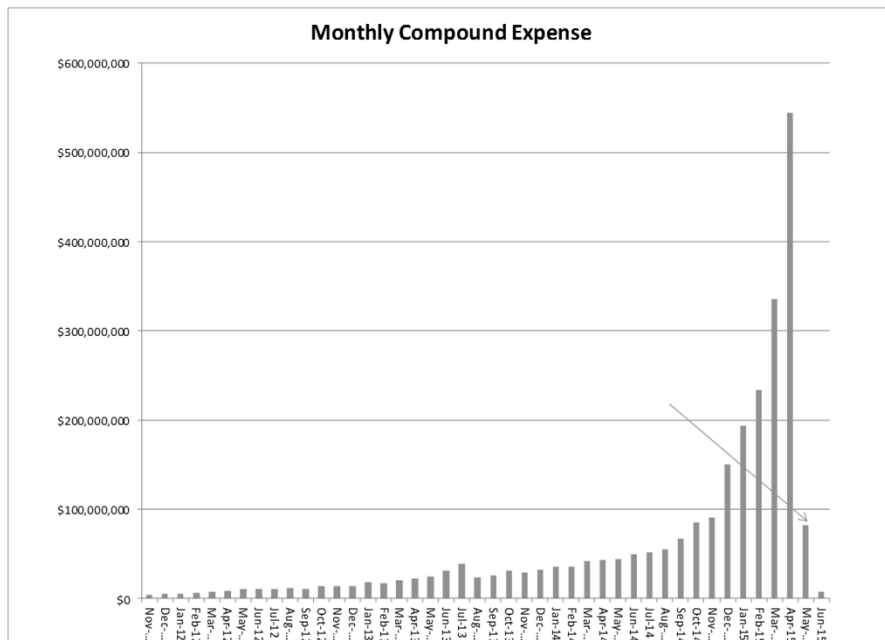


The Compound Drug Scheme

- 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”



Monthly Compound Expense



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



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?