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Lawyers Bringing Facts Into Focus

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Pharmaceutical Fraud

Presented to the Texas Association of Special Investigation Units

I. General Introduction

II. Types of Pharmaceutical Fraud

A. Dispensing: Partially filling Rx but charging for full Rx, charging for returns, defective products, Relabeling / Mislabeling, diluting
B. Physicians: Misleading with inaccurate information, perks, kickbacks, prescribing unneeded meds, "Up-coding"
C. Billing Medicare/Medicaid patients higher rates ("340B" program drugs)
D. Good Manufacturing Practices (GMP) violations
E. Theft: Smash and grab, identity theft (News stories displayed on overhead)

III. The Financial and Social Impact of Pharmaceutical Fraud

A. Dollars lost to Insurance Companies, Insureds, and Tax Payers
B. Negative Impact on Public Health and Medical Research

IV. Red Flags / Issues and Facts to watch out for

A. Data Analysis: Unusual / abnormal findings in analysis of kinds and quantities of prescriptions filled and profits
B. Unorthodox corporate structures

V. Pharmaceutical Investigation Tools for Fraud Diagnosis

A. List of Resources: Provide handout to participants listing various pharmacy research websites and associations providing information on licensing, codes, terminology, etc.
B. Investigation Tools: EUO's, Interviews, Subpoenas, Demand letters, Search Warrants, visit by fiscal intermediary or other fraud agent, OIG Immediate Access Letter, Use data to I.D. key witnesses, etc.
C. Unique yet complimentary roles of SIU, attorneys, and various government pharmaceutical fraud enforcement authorities.

VI. Rules, Regulations, and Available Remedies

A. *Texas Administrative Code*, Title 22, Sec. 291.29 designed to combat "pill mills," including internet sales.
B. Review of other state remedies
C. Federal
   1. Qui tam provisions of the *Federal False Claims Act*
   2. Newly passed health care reform legislation revisions designed to combat pharmaceutical fraud, and areas that remain vulnerable.

VII. The Progression of an Actual Pharmaceutical Fraud Claim: A Case Study Analysis

A. Display and discuss with the participants an outline of a claim, based on a composite of actual claims.
B. Solicit feedback from the audience participants on any red flags they observe, areas they would probe, how to proceed with an investigation.
C. Conduct discussion with participants regarding the initial stages of the investigation. Provide the audience with specific questions to ask during an investigation, who should be questioned, what documents should be requested, what to look for, what authorities to notify, and any reporting deadlines.
D. Unveil additional facts in the claim investigation and discuss how this affects the claim analysis and how to proceed.
E. Summarize the actual outcome of the claim investigation and processing.

VIII. Highlight some Recent and Significant Cases and Settlements throughout the U.S.

IX. Conclusion – Question and Answer