Manufactured Compound Drugs Fraud (MCDF) occurs when pharmacies mass-produce mixed-medication compound drugs, which are normally created for the treatment of specific individuals. Pharmaceutical compound drugs are a useful and legal tool that healthcare providers often use for those with conditions that make normal treatment challenging. Complications with allergies, chronic illnesses, chemical absorption, and the need for irregular quantities are all examples of this. Any such fraud perpetrated against government health programs like Medicare, Medicaid, Tricare, and Workers' Comp falls under the purview of the False Claims Act (FCA).

Overview

Manufactured compound drugs have become a multi-billion dollar business within the healthcare industry. As these products are created for the select needs of individual patients, the FDA alone does not have the means to subject the vast number of them to clinical trials and tests. A legal compound must be clinically effective, critical to the patient's health and not already commercially available in another form. The discretion of physicians and pharmacists is required, which has provided a loophole for some to bypass FDA approvals.

The fastest growing and most controversial sector of the compound drug market is the multi-billion dollar "compound cream" industry. These products are touted for their use in pain relief, but lack the clinical trials or evidence of effectiveness to merit FDA approval. This makes them ineligible for Medicare/Medicaid. However, their purported application in treating pain has allowed them participation in the Workers' Comp insurance program and the Tricare health insurance agency of the US military.

Following a wave of deregulation in California that has migrated nationwide, compound pharmacies are now permitted to charge per each individual ingredient instead of the most expensive active ingredient. As some of these creams list hundreds or even thousands of ingredients—some of which may not even be present—this has resulted in exorbitant price markups. In one ongoing Federal investigation, compound creams with an estimated wholesale cost of around $40 were being sold and submitted to Tricare for thousands of dollars.

The Costs and Dangers of MCDF

The Food and Drug Administration Modernization Act of 1997 exempted compounded drugs from government regulation on the condition that manufacturers not advertise them directly to the public. However, this restriction was removed in a 2002 US Supreme Court decision that ruled that such restrictions were a violation of free speech. Since that time, consumer marketing campaigns and celebrity endorsements have driven up demand by targeting senior citizens and Tricare customers.

The growing use of compounds, along with a lack of consistent FDA regulation, has allowed government assistance programs to be defrauded and for public health to be endangered. As patients cannot verify the effectiveness or safety of medication before their usage, they are

dependent upon safeguards that can fail in a climate of self-regulation. The results of this can be disastrous.

However, new guidelines were passed in 2015 that gave Tricare the authority to verify ingredients in all products created at compound pharmacies. The goal is to reduce the overall number of compounds being used by disallowing non-FDA approved items. Nevertheless, Tricare spent $1.75 billion in 2015 for compounded drugs, an amount 18 times higher than what was spent 3 years earlier.

MCDF on the Rise

MCDF has been identified by several legal scholars and pharmaceutical industry insiders as the new frontier of US Department of Justice (DOJ) healthcare fraud investigations. Qui tam whistleblowers can play a critical role in exposing such practices. Company executives, factory workers, and sales representatives may have access to information regarding mass production strategies that violate compound drug laws.

Some historical cases of MCDF include:

- March 2015: The New England Compound Center (NECC) established a court-ordered fund of $200 million for the victims of a fungal meningitis outbreak arising from company negligence and criminal misconduct. The contamination stemmed from an injectable methylprednisone acetate steroid that the company compounded, used to treat neck, back, and joint pain. As the drug grew more popular, the NECC increased production by over 1,000% and began mass-distribution to the public. The quality control apparatus of the small company became overwhelmed, and thousands of compounds became compromised by foreign contaminants. Since the story first broke in 2013, 64 people have died and over 800 sickened have been afflicted by meningitis, strokes, and spinal infections. The truth was eventually revealed by whistleblower insiders. Over a dozen company founders and executives are currently awaiting trial on criminal racketeering charges.

- May 2015: The DOJ settled with MediMix for $3.8 million over allegations that the company received compounding business from an "improper referral source." Over a 5 year period, Dr. Ankit Desai referred hundreds of compound pain prescriptions through the Tricare program, without disclosing that his wife was a Medimix Senior Vice President. This conflict of financial interest made the referrals ineligible for Tricare reimbursement.

- July 2015: Florida's Blanding Health Mart Pharmacy paid $8.5 million to the US Attorney's office for breaking the FCA and compound manufacturing laws. The company has been charged with prescribing compounds that were medically unnecessary,

sometimes to patients that doctors had not even met. These improper prescriptions were submitted to Tricare, violating the terms of the FCA.

- February 2016: Following a series of raids and property seizures, the FBI and DOJ announced their ongoing investigation into half a billion dollars worth of fraud in the compound cream industry. These include compound creams submitted to Tricare costing upwards of $10,000 that may have no medicinal value. This violated the FCA.