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Federal Task Force Targeting Health Care Fraud in New Jersey for Compound Medications

by Sharmila Jaipersaud, Esq.

The U.S. Attorney's Office and the Department of Justice have formed a federal task force (the "Task Force") focusing on Heath Care Fraud in New Jersey. The Task Force has uncovered fraud schemes in pharmaceutical sales of expensive compound medications that were being prescribed on an unnecessary basis. Most of these compound medications were pain creams, scar creams, wound creams, and hormone replacements.

According to the U.S. Food and Drug Administration (the "FDA"), medication compounding is when a pharmacist or physician "combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of the individual patient." U.S. Food and Drug Admin., *Compounding and the FDA: Questions and Answers*, FDA.GOV (last updated June 22, 2018).

These compounded medications are not commercially available. If a patient is unable to tolerate a commercially available drug, the patient may need an altered drug based on his or her health care provider's medication order. Compounding of medications is regulated by state boards of pharmacy.

Compounding medications is expensive. It requires special training and equipment to create the medications. Additionally, there is a high reimbursement rate from third party payors for compounded medications, which is a key factor that leads to the abuse and fraud. For example: In 2004, TRICARE spent approximately \$5 million for compounded prescriptions. By 2010, the cost had risen to \$23 million. In the first nine months of 2015, TRICARE paid \$1.7 billion for compounded drugs. See Kerry B. Harvey and Andrew L. Sparks, *Prescription for Fraud: Government Enforcement Activities in Compounding Pharmacies*, The National Law Review, February 26, 2018.



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The Task Force is focusing on medication compounding in its efforts to deter fraud. Until now, most health care fraud cases were brought to the U.S. Attorney's Office through whistleblowers or citizens. However, a key component of the Task Force will be data sharing. If there is data that indicates a doctor is filing a significant number of claims for more expensive compound medications or procedures, a red flag will go up. The U.S. Attorney's Office in New Jersey, headed by Craig Carpenito, has indicated that his office is aggressively going after these cases.

For example, on October 15, 2018, the U.S. Attorney's Office announced that Kristie Masucci, of Cedar Run, New Jersey, pled guilty to conspiracy to commit health care fraud. Masucci was a recruiter in the conspiracy and persuaded individuals in New Jersey to obtain very expensive and medically unnecessary medications from an out-of-state pharmacy. Additionally, Masucci and her conspirators, Matthew Tedesco, a pharmaceutical sales representative, and Robert Bessey, recruited public employees covered by the New Jersey State Health Benefits Program and the School Employees' Health Benefits Program to fraudulently obtain compounded medications. Masucci and her conspirators had prescriptions signed by Dr. John Gaffney, who never evaluated whether the patients had a medical necessity for the compounded medication. In return, the pharmacy paid Masucci a percentage of each prescription filled. Masucci faces up to ten years in prison and a maximum fine of \$250,000 for the conspiracy to commit health care fraud charge.

In a related case, from September 2017, New Jersey physician, John Gaffney, pled guilty for selling his signature and for signing prescriptions for patients he never saw. This was part of an elaborate plan, where Gaffney signed prescriptions for compounded medications. He also signed a blank prescription form, which co-conspirators used to submit additional fake prescriptions to the pharmacy. Gaffney was one of 21 defendants involved in the case. There were approximately 200 fraudulent prescriptions filled after Gaffney signed them. The fraud resulted in more than \$24 million being paid out fraudulently. Gaffney was paid \$25,000 for his part and received gifts, including dinners and bottles of wine. As a part of his plea agreement, Gaffney must forfeit the \$25,000 and pay restitution of over \$24 million. Gaffney and the other defendants are awaiting sentencing, which could be as many as ten years in prison.

On October 12, 2018, the U.S. Attorney's Office issued a press release announcing that a federal grand jury indicted Jason Nardachone, a public-school teacher, with conspiracy to commit health care fraud. Nardochone and others received medically unnecessary compounded medications, costing the New Jersey School Employees Health Benefits Program anywhere from \$3,300 to \$22,800 per medication.

These cases illustrate the recent enforcement efforts to stymie health care fraud schemes involving compound medications in New Jersey. If a physician is found to be in violation of these health care fraud and abuse laws, the physician could face both civil and criminal consequences, including: state licensure and disciplinary issues, loss of privileges at hospitals, termination of payor contracts, restitution payments and years in prison. These kinds of cases will be subject to aggressive prosecution and will likely not be contained to New Jersey. Physicians and other health



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care providers should be leery of any marketing plans that offer payments in return for writing compounding medication prescriptions. Any incentives offered to physicians should be scrutinized and prescriptions should only be provided when medically necessary.

For more information, contact Sharmila D. Jaipersaud, Esq. at sdj@spsk.com, or 973-631-7845.

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