DOJ Levels False Claims Act at Pharmacies to Combat Opioid Crisis

February 14, 2019 – FCA Now
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This month the Department of Justice brought a "first of its kind" action against two pharmacies, their owner, and three pharmacists for allegedly dispensing and billing Medicare for prescriptions in violation of both the Controlled Substances Act (CSA) and the False Claims Act (FCA). *See United States v. Oakley Pharmacy, Inc., et al.*, No. 2:19-cv-00009 (M.D. Tenn). The action, seeking both injunctive relief and civil monetary penalties, is a coordinated effort by the Department's Prescription Interdiction & Litigation (PIL) Task Force, which is committed to using "all available . . . tools," including the FCA, "to reverse the tide of opioid overdoses in the United States." In August 2018, the Department filed its first civil action under the CSA and FCA enjoining *prescribers* from "recklessly and unnecessarily distribut[ing] painkillers and other drugs." It is now clear that the Department will also target the pharmacies that *fill* illegitimate prescriptions, and that pharmacists can no longer claim they are following "doctor's orders" to avoid enforcement action.

The action alleges that several pharmacies, their owner, and several pharmacists (collectively "Defendants")

1. knowingly dispensed controlled substances without a valid prescription in violation of 21 U.S.C. § 842(a)(1);
2. knowingly and intentionally distributed and dispensed controlled substances outside the usual course of the professional practice of pharmacy, in violation of 21 U.S.C. § 841(a); and
3. billed Medicare programs to pay for controlled substances that were not used for a medically accepted indication and lacked a legitimate medical purpose in violation of the FCA, 31 U.S.C. 3729, *et seq.*

Controlled Substances Act Violations

Under the CSA and implementing regulations, a prescription is legally valid only if it is issued for "a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). Here, the Defendants

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allegedly dispensed prescriptions outside the usual course of professional practice and in violation of their responsibilities to ensure that prescriptions were issued for legitimate medical purposes.

The Government alleges that a "pharmacist is required to refuse to fill a prescription if he or she knows or has reason to know that the prescription was not written for a legitimate medical purpose," and has a corresponding legal duty to recognize "red flags" that raise a reasonable suspicion that a prescription for a controlled substance is not legitimate. Defendants allegedly ignored "red flags" and warning signs of abuse, such as prescriptions for unusually high dosages of opioids, dangerous combinations of opioids and other controlled substances, and prescriptions from patients travelling long distances to have their prescriptions filled. According to the Complaint, of the 68,000 community pharmacies in the United States, only three bought more opioid doses per capita than defendant Dale Hollow over the last three years.

False Claims Act Violations

The Government appears to assert an *Escobar* implied false certification theory under the False Claims Act. In submitting claims for reimbursement for drugs dispensed to Medicare beneficiaries, pharmacists must certify compliance with all federal laws, regulations, and Centers for Medicare & Medicaid Services' instructions, including the CSA. Further, pharmacists must certify that the data determining payment is accurate, complete, and truthful to the best of their knowledge, and this certification is material to the Government's payment decision. 42 C.F.R. § 423.505(k). Claims for reimbursement that do not have a medically accepted indication do *not* contain accurate, complete and truthful information about the request for payment.

The Government alleges that Defendants dispensed "scores of controlled substance prescriptions" that did not constitute valid prescriptions complying with federal and state law, and were not issued for a legitimate medical purpose or for a medically accepted indication. Medicare does not cover drugs unless they have a medically accepted indication, are reasonable and necessary, and/or are issued for a legitimate medical purpose. Had Medicare known the prescriptions were illegitimate and invalid, the Government argues, it would not have paid for the controlled substances medications. Instead, from 2012 through 2018, Medicare paid one of the pharmacies over $1.4 million for controlled substances, over $1 million of which was for opioids alone.

DOJ Enforcement Trends

This action is the latest in a string of enforcement efforts by the Department to leverage existing tools to combat the prescription opioid crisis, which the Trump Administration declared a national public health emergency in 2017. Since then-Attorney General Jeff Sessions announced the PIL task force in February 2018 (which itself is an outgrowth of the Opioid Fraud and Abuse Detection Unit), the Department has prioritized enforcement actions against opioid manufacturers, distributors, and prescribers, as opposed to opioid users. At the Department's National Opioid Summit in October, Deputy Attorney General Rod Rosenstein stressed that the Department would use "every tool – including both

criminal and civil enforcement powers – [to] cut off the supply of pills from corrupt doctors and pharmacists." That effort is now clearly underway.