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# Strengthen compliance to avoid management's liability for opioid diversion

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Virtually no one disputes that we are in the middle of an opioid and fentanyl epidemic in the United States. Regardless of where one falls on the political spectrum, there is a recognition that prescription drug abuse is a crisis and is one of the biggest dangers to all of our communities. It leads to addiction, accidental death, and violence in our streets; and the cause of that devastation is in our medicine cabinets — and in controlled substance storage facilities at healthcare institutions.

The United States Department of Justice (DOJ) has recently announced a full-throated response to the crisis, reflecting a clear resolve to use every tool in the government's toolbox to combat prescription drug abuse. Although much of the government's efforts will target the illegal importation of fentanyl compounds manufactured in clandestine laboratories overseas, the government has stated its clear intention to prevent the illegal diversion of highly addictive drugs from healthcare institutions. Diversion is the removal of prescription drugs from intended recipients to others, typically for illicit purposes.[1]

There is reason to believe that the government may turn to holding officers, managing employees, and even general counsel of health systems accountable for illegal diversion of opioids under the Responsible Corporate Officer (RCO) doctrine.[2] This may create a dilemma for a healthcare institution's executive staff who, in seeking to avoid prosecution of the business entity through "cooperation credit" by disclosing individual wrongdoing, may simultaneously risk criminal sanction under the RCO, because the conduct occurred under their supervision.[3]The United States Attorney's Manual (USAM) states, "cooperation is a mitigating factor, by which a corporation… can gain credit in a case that otherwise is appropriate for… prosecution." [4]

The solution to this dilemma lies in strengthening a healthcare system's compliance program. In February 2017, the DOJ's Fraud Section issued guidance on how it evaluates compliance programs.[5] It would be prudent for healthcare systems to re-evaluate their programs in light of the government's commitment to fighting the opioid crisis with every weapon (and prosecution theory) available.

## The government's announced response to the opioid crisis

Since 2016, the government has ramped up its effort to combat the growing opioid epidemic. On September 21, 2016, United States Attorney General Loretta E. Lynch directed all United States Attorneys to draft a district-specific strategy aimed at addressing the opioid crisis.[6] On June 6, 2017, Deputy Attorney General Rod J. Rosenstein addressed law enforcement safety when encountering fentanyl, particularly if it becomes aerosolized and is accidently inhaled.[7] On October 17, 2017, Rosenstein announced enforcement action to interdict deadly fentanyl and other opioids from entering the country;[8] on November 1, 2017, Attorney General Jeff Sessions announced fentanyl safety recommendations for first responders;[9] and on November 9, 2017, the DOJ

announced the scheduling of all fentanyl and fentanyl-related analogues as controlled substances.[10] Most recently, on November 29, 2017, Sessions directed each U.S. Attorney to designate an "opioid coordinator" by December 15, 2017 who will: (1) facilitate the intake of opioid and fentanyl cases; (2) convene law enforcement task forces to identify opioid cases for federal prosecution; and (3) provide legal advice and training on opioid prosecutions.[11]

## Health systems diversion prosecutions

Historically, the government has prosecuted a number of cases involving diversion of opioids from healthcare systems by a myriad of healthcare professionals. In 2014, Dignity Health agreed to pay $1.55 million to resolve allegations that its compliance procedures and controls failed to prevent diversion of over 20,000 oxycodone tablets.[12] In 2015, Massachusetts General Hospital agreed to pay $2.3 million to resolve allegations that lax controls enabled its employees to divert approximately 16,000 oxycodone pills from automated dispensing machines.[13] In 2016, Appalachian Regional Healthcare, Inc. agreed to resolve allegations that its pharmacy filled improper prescriptions written by an ER physician.[14]