

# Drug tampering and product substitution in healthcare facilities

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*With opioid diversion continuing to challenge healthcare facilities, the author provides advice on preventing it, spotting perpetrators, and responding to suspected crimes.*

The opioid crisis is one of the largest and most complex public health tragedies that our nation has faced. The toll of addiction in lost lives and broken families touches every community in America.

The U.S. Food and Drug Administration is deeply concerned about the growing epidemic of opioid abuse, dependence, and overdose in the United States. Unfortunately, the medical community can be fertile ground for opioid abuse.

A recent report in *Drug Diversion Digest* showed that more than 70 percent of medication tampering, fraud, and theft occurred in hospitals, medical centers, ambulance services, long-term care facilities, and pharmacies [1]. Thirty percent of this type of medication theft took place in private-practice settings. The report also indicated that the organizations' losses included more than \$162 million and 18.7 million pills. Nearly 95% of those

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reported incidents involved at least one type of opioid.

Opioid addiction or abuse by those in the medical community may lead to tampering. As part of FDA's efforts to address the epidemic of opioid misuse and abuse, the agency's Office of Criminal Investigations (OCI), the primary federal law enforcement agency responsible for drug tampering investigations [2], is working to bring the full force of its criminal investigative powers to the issue of medication tampering.

Below, I highlight information I hope will be useful for detecting drug diversion and understanding the key law relating to it. (The information about steps to take is based on OCI agent observations and is intended for educational purposes only.)

### **RED FLAGS OF TAMPERING AND POTENTIAL DRUG ABUSE BY EMPLOYEES**

Here are some key warning signs that would indicate drug tampering is occurring:

- missing, manipulated, or broken tamper-evident seals

- patient complaints of ineffective pain medication
- higher-than-average narcotic waste by a specific employee
- large number of cancellations on dispensing machines by one employee
- employee wearing long sleeves in warm weather
- employee taking frequent trips to the bathroom
- use of a multi-dose vial when a single-dose vial is available
- treating a patient with a narcotic when other drugs are more appropriate
- employee being in areas where they do not belong or volunteering to do tasks near narcotic supplies
- employee disappearing for long periods of time
- lethargic behavior
- exhibition of opioid withdrawal symptoms, including
  - anxiety, agitation, nausea, vomiting, or abdominal pain
  - uncharacteristic emotional outburst or verbal response

It is also wise to be alert to employees who might have devel-

oped an addiction as a result of a recent injury or surgery that required pain medication.

**RESPONDING TO POTENTIAL TAMPERING**

- Contact FDA-OCI if tampering of any prescription drug is suspected. (You also have a responsibility to notify the Drug Enforcement Administration of lost or stolen controlled substances.)
- Drug-test the suspected employee right away.
- Test the suspected employee for blood-borne pathogens. (Contact an attorney to establish the testing procedures.) Pathogens can be a sign of injection with unsterile syringes.
- Gather and quarantine all potential evidence.
- Keep a chain-of-custody log.
- Document the suspected employee’s behavior.
- Document conversations with the suspected employee.

**PROACTIVE STEPS FOR PREVENTION**

- Witness and document narcotic waste.

- Place surveillance cameras near automated dispensing machines.
- Place surveillance cameras in areas to monitor sterile supply items and non-controlled medications.
- Conduct regular, facility-wide audits of narcotic use.
- Provide access to peer assistance programs.

**THE KEY LAW CONCERNING PRODUCT TAMPERING AND SUBSTITUTION**

The Federal Anti-Tampering Act [3] indicates that “Whoever, with reckless disregard for the risk that another person will be placed in danger of death or bodily injury and under circumstances manifesting extreme indifference to such risk, tampers with any consumer product that affects interstate or foreign commerce, or labeling of, or container for, any such product, or attempts to do so, commits product tampering.” [See 18 USC 1365(a).]

To be more specific:

- The Federal Anti-Tampering Act considers food, drugs, medical devices, and cosmet-

## PRODUCT TAMPERING CASES IN THE NEWS

Some recent examples of criminal cases involving opioid tampering:

“Former Roanoke-Area EMS Worker Sentenced for Tampering with Fentanyl and Hydromorphone” <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/former-roanoke-area-ems-worker-sentenced-tampering-fentanyl-and-hydromorphone>

“Former Nurse Charged with Tampering with Consumer Products” <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/former-nurse-charged-tampering-consumer-products>

“Connecticut Nurse Sentenced for Tampering with Liquid Morphine” <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/connecticut-nurse-sentenced-tampering-liquid-morphine>

“Federal Jury Finds Former Nurse Guilty of Fraudulently Obtaining and Tampering with Opioid Pain Killer” <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/federal-jury-finds-former-nurse-guilty-fraudulently-obtaining-and-tampering-opioid-pain-killer>

“Former West Boylston Nurse Sentenced for Tampering with Hydromorphone and Meperidine” <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/former-west-boylston-nurse-sentenced-tampering-hydromorphone-and-meperidine>

“Former Roanoke Pharmacist Pleads Guilty to Tampering” <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/former-roanoke-pharmacist-pleads-guilty-tampering>

- ics to be *consumer products*.
- It is not necessary for death or bodily injury to occur.
- It is not necessary to prove that the suspect intended to cause death or bodily injury.
- All that is required is that, as a result of the tampering, death or any bodily injury *could have happened*.
- *Bodily injury* is any physical or mental injury, however slight, no matter how temp-

orary. (The Act defines bodily injury as a cut, abrasion, bruise, burn, or disfigurement; physical pain; illness; impairment of the function of a bodily member, organ, or mental faculty; or any other injury to the body, no matter how temporary. [See (18 USC 1365(h)(4)]

## WHAT TO KNOW ABOUT OCI SPECIAL AGENTS

OCI special agents investigate criminal allegations falling within the FDA's jurisdiction. They are uniquely equipped to protect the public health in today's global and continually changing environment.

The agents have training in traditional law enforcement methods and investigative techniques to bring their cases to a successful conclusion. They have authority to obtain and execute arrest and search warrants, carry firearms, and gather evidence to enforce federal criminal laws.

In addition, OCI special agents must successfully complete a rigorous schedule of specialized trainings including: the U.S. Department of Homeland Security's criminal investigative training program, the FDA Special Agent

Training Program, an FDA law course administered by the agency's Office of Chief Counsel, and a U.S. criminal law course from the U.S. Department of Justice.

OCI's special agents often operate in a specialized, science-based environment, so they receive continuing advanced instruction in FDA food and drug law, interviewing techniques, financial crimes, computer forensics, asset forfeiture, legal education, and internet investigations. Many agents also receive specialized training in support of investigations focused on pharmaceutical drugs (human and animal), medical devices, food, biologics, and tobacco.

To contact local OCI offices, call OCI headquarters at 1-800-551-3989 or visit the OCI website at <https://go.usa.gov/xsjVb>

### References

1. Protenus, Inc. (2018, January–June). 2018 six-month retrospective: 18.7M pills lost due to healthcare employee misuse and theft. *Drug Diversion Digest*. <https://bit.ly/3jRxG1x>
2. U.S. Food and Drug Administration. *Criminal investigation*. Retrieved February 15, 2021, from <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/criminal-investigations>
3. Tampering with Consumer Products, 18 U.S. Code § 1365. <https://corpuslegalis.com/us/code/title18/tampering-with-consumer-products3>