



Healthcare Facility Response

- Contact FDA-OCI if tampering of any Rx Drug is suspected
- Drug-test suspected employee(s) right away*
- Test suspected employee(s) for blood borne pathogens*
- Gather and quarantine all potential evidence
- Keep a chain-of-custody log
- Document suspected employee's behavior
- Document conversations with suspected employee(s)

** Consult an attorney to establish these procedures*

Office of Criminal Investigations U.S. Food and Drug Administration

For Information or Assistance:

OCI Headquarters	1-800-551-3989
Chicago Office	1-800-521-5782
Kansas City Office	1-800-453-7149
Dallas Office	1-800-469-3088
Los Angeles Office	1-800-453-4034
San Francisco Office	1-800-786-5241
Metro Washington Office	1-800-521-5783
Philadelphia Office	1-877-344-4965
Miami Office	1-800-453-7151
Atlanta Office	1-888-544-9198
New Orleans	1-866-663-3343
San Juan Office	1-787-729-8770
New York Office	1-800-332-4813
Boston Office	1-781-224-4848

To learn more go to www.fda.gov/oci



The Office of Criminal Investigations, within the Office of Regulatory Affairs, is the law enforcement arm of the U.S. Food and Drug Administration. OCI conducts and coordinates criminal investigations regarding possible violations of the laws relating to FDA-regulated products, concentrating on significant violations of these laws, with a priority on conduct that may present a danger to the public health.

Note

Reporting a tampering incident to FDA-OCI does not replace your responsibility to notify the DEA of lost or stolen controlled substances.

This information is based on agent observations and is intended for educational purposes only.



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Drug Tampering in Healthcare Facilities

- Opioid Abuse
- Warning Signs
- Prevention
- Facility Response





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Opioid Abuse

- The U.S. FDA is deeply concerned about the growing epidemic of opioid abuse, dependence, and overdose in the United States
- The medical community can be fertile ground for opioid abuse
- Opioid addiction/abuse by those in the medical community may lead to drug tampering

AMBULANCE ONLY



Warning Signs

- Tamper-evident seals are missing, manipulated, or broken
- Patients complain of ineffective pain medication
- Higher-than-average narcotic waste by a specific employee
- Large number of cancellations on dispensing machines by one employee
- Employee who may have developed an addiction due to recent injury or surgery that required pain medication
- Long sleeves in warm weather
- Frequent trips to the bathroom
- Using a multi dose vial when a single dose vial is available
- Opting to treat the patient with a narcotic when other drugs are more appropriate
- Being in areas they don't belong or volunteering to do tasks near narcotic supply
- Disappearing for long periods of time
- Lethargic behavior
- An employee exhibits opioid withdrawal symptoms, including:
 - o Anxiety, agitation, nausea, vomiting, or abdominal pain
 - o Uncharacteristic emotional outburst or verbal response



Prevention

- Narcotic waste should be witnessed and documented
- Surveillance cameras near automated dispensing machines
- 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