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

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.
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.

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:
  - Anxiety, agitation, nausea, vomiting, or abdominal pain
  - 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