



# Nevada State Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## CS: Reporting Theft or Loss

The Nevada State Board of Pharmacy has seen an increase in questions regarding the reporting requirements for theft or loss of controlled substances (CS). Typical questions include: When should a pharmacy or a CS registrant report missing or stolen CS? How should theft or loss be reported, and how soon after discovery? Does Nevada’s reporting requirement mirror federal Drug Enforcement Administration (DEA) requirements?

Nevada’s reporting requirement is set forth in Nevada Revised Statutes (NRS) 453.568:

All loss or theft of controlled substances must be reported on forms provided by the Division to the Board and Division within 10 days after the date of discovery of the theft or loss.

The federal reporting requirement is set forth in both Title 21 Code of Federal Regulations (CFR) §1301.74(c) Other security controls for non-practitioners and Title 21 CFR §1301.76(b) Other security controls for practitioners:

The registrant [must] notify the Field Division Office of the [Drug Enforcement] Administration in his [or her] area, in writing, of any theft or significant loss of any controlled substances within one business day of discovery of the theft or loss.

Nevada requires “all loss or theft” to be reported to the Board within 10 days of discovery of the theft or loss, whereas DEA requires the reporting of “theft or significant loss” to a DEA Diversion Control Field Office within one business day of discovery. Nevada allows 10 days to

permit the registrant sufficient time to investigate and more thoroughly report the circumstances surrounding the loss or theft. Additionally, NRS 453.568 is very clear in that **any** loss or theft must be reported.

The law references reporting to both the Board and to the Division, which is the Nevada Department of Public Safety, Investigation Division. The Division co-administers the Nevada Prescription Monitoring Program with the Board, pursuant to NRS 453.162, and both agencies work closely to prevent the illegal prescribing of CS that can result in diversion, abuse, and overdoses. The Nevada Department of Public Safety provides services in support of protecting Nevada’s citizens and visitors by promoting safer communities through prevention, preparedness, response, recovery, education, and enforcement. (More information can be found at [www.dps.nv.gov](http://www.dps.nv.gov).)

The Division requires losses or thefts to be reported using DEA Form 106, which can be found at <http://deacompliance.com/downloads/DEA%20Form%20106.pdf>. Merely a letter or corporate communication stating that a loss or theft has occurred does not satisfy the reporting requirement.

Once the DEA Form 106 has been completed, remember that the form must be forwarded to:

1. The Nevada State Board of Pharmacy (fax: 775/850-1444);
2. The Nevada Department of Public Safety, Investigation Division (fax: 775/684-7450, Attention: Coley); and
3. DEA Diversion Control Field Office

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# National Pharmacy Compliance News

July 2019



**NABPF**  
National Association of Boards  
of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

## ***FDA Changes Opioid Labeling to Give Providers Better Information on Tapering***

Noting that the agency remains focused on striking the right balance between policies that reduce the rates of opioid addiction while still allowing patients and health care providers access to appropriate pain treatments, Food and Drug Administration (FDA) has announced required changes to the prescribing information for all opioid analgesic medications used in the outpatient setting. The changes, announced in a [Drug Safety Communication](#), provide expanded information to health care providers on how to safely decrease the dose in patients who are physically dependent on opioids. FDA intends for this information to be used when health care providers and patients have decided together that a decrease in dose or discontinuation of opioids is appropriate.

“Rapid discontinuation can result in uncontrolled pain or withdrawal symptoms. In turn, these symptoms can lead patients to seek other sources of opioid pain medicines, which may be confused with drug-seeking for abuse,” the agency said in the communication. “Patients may attempt to treat their pain or withdrawal symptoms with illicit opioids, such as heroin, and other substances.”

In addition to these changes, an FDA press release also announced that additional policies related to the opioid crisis are forthcoming. These include a requirement for immediate-release formulations of opioids to be made available in fixed-quantity packaging that contain doses more typical of what patients may need for common acute pain conditions and procedures. The full press release is available in the [News and Events section](#) of the FDA website.

## ***DEA Warns of Scam Calls Targeting Pharmacists and Other DEA-Registered Providers***

Health care providers and other members of the public have reported receiving phone calls from people claiming to represent Drug Enforcement Administration (DEA), and threatening legal action against them if a large fine is not paid immediately over the phone. According to a [DEA press release](#), this scam used fake names and badge numbers, or the names of well-known senior officials with DEA, and threatened victims with arrest,

prosecution, imprisonment, and revocation of their DEA numbers. The agency emphasizes that DEA will never contact practitioners by phone to demand money or any form of payment. DEA will not request any personal or sensitive information by phone, and notification of legitimate investigation or legal action is made via official letter or in person.

DEA asks anyone who receives a call from a person purporting to be a DEA special agent or other law enforcement official asking for money to refuse the demand and report the threat using the [online form](#) or by calling 877/792-2873. Reporting these calls will assist DEA in investigating and stopping this activity.

## ***FDA Officials Outline 2019 Efforts to Improve Quality of Compounded Drugs***

Recognizing the important roles compounded drugs can play in patient care, FDA plans to continue its efforts to improve the quality of compounded drugs. According to a statement posted to the FDA website, these priorities include:

- ◆ maintaining quality manufacturing compliance,
- ◆ strengthening and refining regulations on compounding from bulk drug substances,
- ◆ finalizing the agency’s memorandum of understanding with the states, and
- ◆ issuing revised draft guidance for compounding by hospital and health systems.

“We’ve worked to refine our existing practices, shape new policies and increase the frequency of our communications with industry, Congress, states and patients concerning our programs,” then-Commissioner Scott Gottlieb, MD, and Deputy Commissioner Anna Abram said in a [statement](#) published on the FDA website. “We anticipate that 2019 will be an equally productive year for the FDA’s compounding program, with better quality continuing to be our top priority as part of our ongoing effort . . . to improve the quality of compounded products for consumers . . .”

In addition, Gottlieb and Abram’s statement notes that the agency will continue to work closely with stakeholders on these steps and any other compounding-related measures not outlined in the statement.

## **China Agrees to Stricter Fentanyl Production Laws Following Pressure From US Lawmakers**

China has announced that all variations of the powerful opioid product, fentanyl, will be treated as controlled substances (CS). According to a [press release](#) from Senator Tom Cotton, the announcement came after a bipartisan group of United States lawmakers, including Cotton, introduced Senate Bill 1044, a bill designed to apply pressure to the Chinese government to make all forms of synthetic opioids illegal and to provide US law enforcement with more tools and resources to go after illicit traffickers in China, Mexico, and other countries.

“Combating the flow of illicit fentanyl into our country is imperative in the fight to save American lives from the opioid crisis,” Senate Minority Leader Chuck Schumer said in the press release. “We must hold China accountable for their role in the fentanyl trade. China’s new regulation to make all fentanyl categories illegal is an important step and the administration deserves praise for their efforts to secure this change. However, we have to demonstrate that we will demand China enforce these laws and take strong action against opioid traffickers.”

In a December meeting with President Donald Trump, China’s President Xi Jinping promised to classify fentanyl as a CS following a 2018 report by the US-China Economic and Security Review Commission that found China to be “the largest source of illicit fentanyl and fentanyl-like substances” in the US, according to a report from NPR. The latest increase in opioid-related overdose deaths has been largely attributed to the availability of illegally manufactured fentanyl.

## **Two Lots of Transdermal Fentanyl Patches Recalled Due to Product Mislabeling**

Alvogen, Inc, of Pine Brook, NJ, is recalling two lots of Fentanyl Transdermal System 12 mcg/h transdermal patches to the consumer level after a small number of cartons were found to contain 50 mcg/h patches. Though the 50 mcg/h patches are individually labeled correctly, accidental application of the higher dosage patch instead of the prescribed 12 mcg/h patch could result in serious, life-threatening, or fatal respiratory depression. The

company has not received any reports of adverse events related to this issue.

The company is notifying its distributors and direct customers by certified letter and is arranging for the return and replacement of all recalled products. Pharmacies are asked to stop dispensing any product subject to the recall. Consumers that have affected products should immediately remove any patch currently in use and contact their health care provider. Patients with unused product should return it to the point of purchase for replacement.

Additional information on the recall, including the affected lot numbers and customer service contact information, is available in a [press release](#) posted to the FDA website. Adverse reactions and quality problems can be reported to the FDA MedWatch Safety Information and Adverse Event Reporting Program.

## **FDA Releases Toolkit to Help Promote Safe Opioid Disposal**

FDA has made a new resource available for consumers and health care providers to help promote and educate individuals about how to safely dispose of unused opioids. The free Safe Opioid Disposal – Remove the Risk Outreach Toolkit includes video, radio, and print public service announcements, social media graphics and posts, fact sheets, drop-in content, and website badges that health care providers and other interested individuals and organizations can use to promote the message of opioid safety. The toolkit and its resources can be accessed on the Ensuring Safe Use of Medicine section of the FDA website.

An additional resource available to help consumers find disposal kiosks available year round is the National Association of Boards of Pharmacy<sup>®</sup> (NABP<sup>®</sup>) Drug Disposal Locator Tool, available in the AWA<sup>®</sup> Rx<sup>®</sup> Prescription Drug Safety section of the NABP website, [www.nabp.pharmacy/initiatives/AWA<sup>®</sup>RxE](http://www.nabp.pharmacy/initiatives/AWA<sup>®</sup>RxE). With more than 6,500 disposal sites in the continually updated database, consumers can enter location information to find the nearest disposal sites to them using a map.

Additional information about the FDA campaign can be found at <https://www.fda.gov/drugs/buying-using-medicine-safely/ensuring-safe-use-medicine>.