



Iowa Board of Pharmacy

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USP <795>, <797>, and <800>

As of December 1, 2019, the Iowa Board of Pharmacy will require full compliance with United States Pharmacopeia (USP) General Chapters <795>, <797>, and <800>. Compliance with USP Chapter <800> will be required for both compounding and non-compounding pharmacies ([657 Iowa Administrative Code \(IAC\) 8.5\(11\)](#)). Compounding pharmacies that are unable to meet certain requirements within USP may apply to the Board to request a delay of the enforcement date. If granted, the maximum amount of time for delayed enforcement will be 18 months. Additional time extensions will not be permitted.

Petitioners were required to submit a completed [Delayed Compliance Petition Form](#) and all required supporting documentation by September 1, 2019. Decisions will be made prior to the Board meeting scheduled for November 5-6, 2019; the potential exists for a requested appearance at this meeting if the application requires full Board approval. Please plan accordingly.

Electronic Prescribing Mandate – January 1, 2020

In 2018, the Iowa Legislature passed legislation that will require all prescriptions, including controlled substances, to be electronically prescribed by prescribers and electronically received by pharmacies, beginning on January 1, 2020.

According to Surescripts data from July 2019, Iowa's e-prescribing activity is still well below the national averages. Of Iowa's prescribers, 67.6% (versus 75% nationally) are submitting electronic prescriptions to pharmacies. A total of 64.1% of Iowa's prescribers have certified and audit-approved software that is capable of transmitting electronic prescriptions for controlled substances (EPCS). Yet, only 38.6% of Iowa's prescribers have enabled this feature within their e-prescribing software (versus 38% nationally).

Conversely, Iowa's pharmacies are on par with the national average for the ability to receive electronic

prescriptions (both are 98.2%), while the rate of EPCS-enabled pharmacies in Iowa hedges out the national averages by just over 2% (97.9% versus 95.3%, respectively).

The legislation requiring e-prescribing permitted several exceptions to the e-prescribing mandate. Prescriptions that are excluded from the mandate include:

1. A prescription for a patient residing in a nursing home, long-term care facility, correctional facility, or jail.
2. A prescription authorized by a licensed veterinarian.
3. A prescription dispensed by a US Department of Veterans Affairs pharmacy.
4. A prescription requiring information that makes electronic submission impractical, such as complicated or lengthy directions for use or attachments.
5. A prescription for a compounded preparation containing two or more components.
6. A prescription issued in response to a public health emergency in a situation where a non-patient-specific prescription would be permitted.
7. A prescription issued pursuant to an established and valid collaborative practice agreement, standing order, or drug research protocol.
8. A prescription issued during a temporary technical or electronic failure at the practitioner's or pharmacy's location, provided that a prescription issued pursuant to this exception shall indicate on the prescription that the practitioner or pharmacy is experiencing a temporary technical or electronic failure.
9. A prescription issued in an emergency situation pursuant to federal law and regulation rules of the Board.

Additionally, a practitioner, medical group, or pharmacy that is unable to timely comply with the electronic prescribing requirements may petition the Board for an exemption based on economic hardship; technical limitations that the practitioner, medical group, or pharmacy

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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[®] (NABP[®]) Drug Disposal Locator Tool, available in the AWA[®] Rx[®] Prescription Drug Safety section of the NABP website, [www.nabp.pharmacy/initiatives/AWA[®] Rx[®]](http://www.nabp.pharmacy/initiatives/AWA[®] Rx[®]). 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>.

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cannot control; or other exceptional circumstances. The Board may grant exception requests for a period of time that may not exceed one year, which may be renewable with Board approval. Exemption petition forms and additional information regarding the e-prescribing mandate can be found on the [Board's website](#).

After the mandate becomes effective on January 1, 2020, **a pharmacist who receives a written, oral, or faxed prescription that is otherwise legitimate will not be required to verify that the prescription is subject to an exception previously listed and may dispense the prescription.** Failure to transmit a prescription as an electronic prescription does not automatically nullify or make the prescription “illegal.” However, a pharmacist must exercise professional judgment in identifying and reporting suspected violations of the e-prescribing mandate to either the Board or the appropriate professional licensing board of the practitioner.

A prescriber who violates this mandate is subject to an administrative penalty of \$250 per violation, up to a maximum of \$5,000 per calendar year. The administrative penalty assessed by the prescriber's primary licensing board will not be considered a disciplinary action or reported as discipline. A practitioner may appeal the assessment of the administrative penalty, which will initiate a contested case proceeding. The administrative penalties collected will be deposited into the drug information program fund to further support and enhance Iowa's prescription monitoring program.

Statewide Protocols

The Board's [statewide protocols](#) for naloxone, nicotine replacement products, and immunizations went into effect on April 5, 2019. Pharmacists acting under the statewide protocol may need to obtain a national provider identification (NPI) number in order to properly bill the prescriptions to third-party payers.

Additionally, the Iowa Legislature postponed the sunsetting of the physician-approved immunization protocols from July 1, 2019, to July 1, 2020. The legislature recognized that additional time may be necessary to ensure that Iowa Medicaid recognizes the pharmacists' NPI number on the claims being submitted for immunizations under the statewide protocol.

Technician Product Verification Programs

The Board adopted final rulemaking to rescind Chapter 40, “Tech-Check-Tech Programs” and adopt

the new Chapter 40, “Technology-Assisted Technician Product Verification Programs.” During the 2018 session of the Iowa Legislature, the IAC was amended to allow technician product verification (TPV) programs in community pharmacies. Previous programs were called tech-check-tech programs and only authorized the practice in a hospital pharmacy or community pharmacy providing care for facility patients when another licensed health care practitioner would be administering the medications. Under the new rules, which became effective June 26, 2019, a pharmacy may establish a TPV program that is intended to redirect pharmacist time to increased clinical services (such as medication therapy management, collaborative practice, statewide protocols, and immunizations). In a pharmacy using a TPV program, **pharmacist hours shall not be reduced but shall be redistributed to clinical pharmacy services to improve patient care and health outcomes.**

Additional TPV program requirements shall include:

- ◆ appropriate scanning technology to ensure that each product is accurately filled and verified
- ◆ no more than three checking technicians per pharmacist involved in the prescription-filling process (institutional settings are exempt)
- ◆ advance notice to the Board of program implementation
- ◆ minimum qualifications for checking technicians
- ◆ quality assurance process
 - ◇ quarterly verification
 - ◇ quarterly reports
- ◆ record keeping

The Board did not authorize “grandfathering” of any previously existing tech-check-tech programs, so pharmacies are expected to be compliant with the revised rules in Chapter 40, unless the pharmacy has received a waiver. The complete chapter is available on the Board's website.

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