



Idaho State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Idaho Pharmacist Prescriptive Authority Updates and Regulations

Following the Idaho Legislature's passage, Governor Brad Little signed House Bill 182 into law this spring. This bill changed Idaho Code Section 54-1704(5)(g), eliminating the need for the Idaho State Board of Pharmacy to specifically authorize certain drugs, drug categories, and devices that may be prescribed by Idaho pharmacists. The law change took effect on July 1, 2019.

In furtherance of the prescribing authority set forth in Idaho Code Section 54-1704(5)(g), the rules setting parameters around pharmacist prescriptive authority remain unchanged. For each drug or drug category, or device that a pharmacist intends to prescribe, the specific requirements can be found in Rule 27.01.01.350, which instructs the pharmacist to:

- ◆ be educationally prepared;
- ◆ have a valid patient-prescriber relationship;
- ◆ maintain a patient assessment protocol based on the applicable standard of care and specify patient inclusion, exclusion, and medical referral criteria;
- ◆ develop and implement an appropriate follow-up care plan;
- ◆ notify the patient's primary care provider, if one is identified by the patient; and
- ◆ document the basis for the patient encounter.

The Idaho rules indicate that the patient assessment protocol is to be used to identify patients who may not be appropriate candidates for treatment by the pharmacist and who may need a referral to a more appropriate venue for care. The Board had published several template protocols that served as a useful starting point for pharmacists in fulfilling their obligations under the general requirements. These specific template protocols now reside with the state associations. Pharmacists are encouraged to develop their own protocols for drugs, drug categories, and devices prescribed within Food and Drug Administration (FDA)-approved labeling that are limited to conditions that:

- ◆ do not require a new diagnosis;
- ◆ are minor and generally self-limiting;
- ◆ have a test that is used to guide diagnosis or clinical decision making and are Clinical Laboratory Improvement Amendments-waived; or
- ◆ threaten the health or safety of the patient if not immediately dispensed.

Information on Medicaid Rules Surrounding Cash Payments for CS

The Board has received several calls regarding the new Medicaid rule. The following information is supplied directly by Medicaid and is published here for your convenience.

Background – Current Medicaid rules state:

Payment in Full. If a provider accepts Medicaid payment for a covered service, the Medicaid payment must be accepted as full payment for that service and the participant cannot be billed for the difference between the billed amount and the Medicaid allowed amount. (3-30-2007) IDAPA 16.03.09.210.04

In the 2019 legislative session, a new rule was also approved:

Prohibition Against Cash Payment for Controlled Substances (CS). Pharmacy providers are prohibited from accepting cash as payment for CS from persons known to be Medicaid participants. (4-11-19) IDAPA 16.03.09.663.07

The term "cash" is meant to refer to any form of private or self-payment, including cash, check, or credit card.

The following frequently asked questions are provided to help pharmacies comply with these rules.

Frequently Asked Questions

Q. Why was this rule put in place?

- A.** The mission of the Idaho Department of Health and Welfare is to promote and protect the health and safety of Idahoans. This new rule aims to ensure the safety of Medicaid participants and other Idahoans.

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National Pharmacy Compliance News

September 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[®] (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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Q. What are the main issues that Idaho Medicaid is concerned with?

A. Currently, Idaho Medicaid's primary concern is opioid overutilization; however, Medicaid is also concerned about overuse of benzodiazepines, carisoprodol, and stimulants.

Opioids

- ◆ Adequate pain relief should be safe and effective. The current Centers for Disease Control and Prevention guidelines for chronic non-cancer pain recommend prescribing the lowest effective opioid dose, assessing individual benefits and risks when considering increasing doses to more than 50 morphine milligram equivalents (MMEs)/day, and avoiding increases to total doses of more than 90 MMEs/day for most patients.
- ◆ While opioids may provide short-term pain relief, there is no evidence that they maintain pain relief, improve a patient's ability to function, or improve quality of life over long periods of time for patients with chronic non-cancer pain. Studies do show, however, that long-term use is associated with an increased risk of overdose, opioid-related adverse events, and opioid use disorder.
- ◆ Idaho Medicaid has made significant strides in limiting newly started patients to a total daily MME less than 90 mg, inclusive of all opioid preparations. Medicaid has also worked with providers to taper down patients currently receiving high doses to much lower doses. Unfortunately, the prescription monitoring program shows that many of these patients continue to pay cash for additional opioids, bringing their total daily MMEs in some cases to 2,000 mg or more.
- ◆ Idaho Medicaid is also concerned with issues of unrecognized opioid-induced hyperalgesia, diversion to non-Medicaid patients, and the circumvention of Medicaid's federally mandated prospective drug utilization edits, which enhance patient safety through evaluation of drug interactions, duplications, and contraindications.

Benzodiazepines

- ◆ Idaho Medicaid is concerned about the concurrent use of multiple different benzodiazepines as well as the use of benzodiazepines together with opioids and other centrally acting central nervous system (CNS) depressants. Medicaid has also noted and is concerned about long-term use of benzodiazepines as monotherapy in anxiety disorders, without any other anxiolytic such as a selective serotonin

reuptake inhibitor or serotonin and norepinephrine reuptake inhibitor.

Carisoprodol (Soma®)

- ◆ Carisoprodol is only FDA-approved for acute treatment with a maximum of three weeks of therapy. Carisoprodol has addictive potential and can increase the risk of overdose when mixed with other CNS depressants.

Q. What should a pharmacy do about prescriptions that patients are currently paying cash for?

A. We do not want to put any participants at risk by abruptly discontinuing their medications. As an agency, we are patient-centered and recognize patient individuality and needs. **Help us help you** by identifying and informing us of Medicaid patients who are currently paying cash for CS. Call the Medicaid pharmacy program at **208/364-1829** or fax us at **800/327-5541**. We will reach out to the prescriber and work with him or her on changing therapy or developing tapering plans. During this transition we will temporarily pay for most of these prescriptions. If you have notified us, you may accept cash for current patients for one full prescription while we work with the prescriber.

Q. What about new prescriptions when the patient requests to pay cash?

A. Encourage the prescriber to contact Idaho Medicaid at **208/364-1829**. We will work with the prescriber to establish an agreed upon dose with future tapering as necessary. You may use the 72-hour emergency override as needed when the dispensing pharmacist's professional judgment deems the prescription medically necessary.

Q. Can the patient lose their Medicaid coverage or can the pharmacy lose their provider status by allowing a cash payment?

A. Again, the primary objective for this rule is patient safety. It is not meant to be punitive. The rule is tied to the Medicaid Provider (Pharmacy) Agreement and there are no consequences for the patient. Idaho Medicaid acknowledges that persons presenting at the pharmacy may not be known to the pharmacy as a Medicaid participant and may not identify themselves as such. Idaho Medicaid will not be looking at isolated or single incidents of cash payments. Idaho Medicaid will be monitoring only for pharmacies repeatedly allowing cash payments over time.

Q. What about drugs that are excluded from payment by Medicaid?

A. Drugs such as codeine cough preparations and drugs used for weight loss, eg, phentermine, which

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are excluded from Medicaid coverage, may still be dispensed for cash at the discretion of the pharmacist, since no pathways such as prior authorization exist for these drugs to be paid for by Medicaid.

Birth Month Renewal Transition Completed and Current Email Renewal Notices

The final transition to birth month renewal for individual licensees and registrants (except pharmacist interns) was completed June 30, 2019. Licenses and registrations will now expire on the last day of the individual's birth month. Courtesy renewal notices will be sent out 10 weeks prior to expiration to the email address on file with the Board. Per Rule 27.01.01.501.02, it is your responsibility to maintain a current email address with the Board. It is also recommended that info@bop.idaho.gov be marked as a "safe" email address to prevent reminders from going into a spam folder. Having individual device settings that filter out courtesy renewal reminders does not suffice as a reason to not renew in a timely manner. Verify that your preferred email is on file with the Board by logging in to [MyLicense e-Gov](#).

Omnibus Reauthorization of Temporary Rules Combines Pharmacy Rules Into Single Chapter

Under the Idaho Administrative Procedures Act, all administrative rules automatically sunset on July 1 unless extended by the Idaho Legislature. This year for the first time, the legislature did not pass the traditional "going-home" bill. As a result, all rules were scheduled to expire.

Governor Little tasked his administration with reauthorizing necessary rules as "temporary and proposed" rules prior to July 1, 2019, so there would be no negative impact on public health, safety, and welfare. Governor Little viewed the situation as an opportunity to reset Idaho's regulations.

At its February 2019 meeting, the Board had already begun a rules review process to comply with Governor Little's executive order establishing the Red Tape Reduction Act, which he issued during his first few weeks in office. In April 2019, the Board hosted an open public meeting to identify which rules to reauthorize or allow to expire. The Division of Financial Management publicly posted the list of rules identified for expiration and solicited public input.

As a result of these efforts, the five chapters of the Board's rules were combined back into a single chapter and are posted on the Board's website. The numbering of the rules has changed and this is a good time to refamiliarize yourself with the current rules.

Click here for the current rules: <https://adminrules.idaho.gov/rules/current/27/270101.pdf>.

The Board is grateful to the many stakeholders who provided input to ensure that the necessary rules were reauthorized. If you have any remaining questions or feedback, please do not hesitate to reach out to Board staff.

Help Is Available for Impaired Pharmacists Through the Idaho PRN

The Idaho State Board of Pharmacy subsidizes the state's Pharmacist Recovery Network (PRN). The primary function of this program is to assist the impaired pharmacist in every aspect of recovery from chemical dependence, including intervention, consultation, monitoring, advocacy, education, and support. If you need confidential help – or know an associate who does – please contact the program's vendor, Southworth Associates, by phone at 866/460-9014.



**Know a Pharmacist in trouble with
drugs/alcohol or mental health problems?**

Please contact the Pharmacist Recovery Network for help.
www.SouthworthAssociates.net 800.386.1695

24 CONFIDENTIAL Toll free Crisis Line
HOUR 866.460.9014

Special Notice

The *Idaho State Board of Pharmacy Newsletter* is considered an official method of notification to pharmacies, pharmacists, pharmacy interns/externs, and pharmacy technicians registered by the Board. Please read it carefully.

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