December 2020

News

Idaho State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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There's Still Time to Obtain CPE Credits for 2020

Continuing pharmacy education (CPE) hours must be obtained each calendar year between January 1 and December 31. Per IDAPA 24.36.01.213, the rules of the Idaho State Board of Pharmacy for CPE requirements are as follows:

> Each pharmacist applicant for license renewal must complete fifteen (15) CPE hours each calendar year between January 1 and December 31.
>
> 1. ACPE. At least twelve (12) of the CPE hours obtained must be from programs by an ACPE that have a participant designation of "P" (for pharmacist) as the suffix of the ACPE universal program number. ACPE credits must be reported to and documented in CPE Monitor in order to be accepted.
> 2. CME. A maximum of three (3) of the hours may be obtained from CME, if the credits are:
>   a. Obtained from an ACCME accredited provider; and
>   b. A certificate is furnished that identifies the name of the ACCME accredited provider and a clear reference to its accreditation status, the title of the CME program, the completed hours of instruction, the date of completion, and the name of the individual obtaining the credit. All CME certificates must be submitted to the Board between December 1 and December 31.
> 3. Alternative to CPE. If audited, a pharmacist may substitute a current certification by a nationally accredited pharmacy practice-specific specialty certification program.

Need help tracking your CPE progress? There is an app for that. The National Association of Boards of Pharmacy® (NABP®) e-Profile app offers a seamless experience using CPE Monitor®. Logging in to CPE Monitor directly from the NABP website is also available using this link.

The law does require the CPE to be documented in CPE Monitor. There is no exemption for new graduates. The expectation is that all licensed pharmacists meet the requirements of IDAPA 24.36.01.213. The current penalty for noncompliance is informal discipline, which includes a fine for each missing hour of CPE as well as the requirement for an additional hour of CPE for every hour the licensee is short. Alternatively, the licensee may appear before the Board in a legal proceeding that may become formal discipline.

Frequently Asked Questions About Immunizations Answered

Q. What is the age limit on pharmacists' prescriptive authority for immunizations in Idaho?

A. At this time, there is no age limit on immunizations for pharmacist prescribing in Idaho. On April 2, 2020, Governor Brad Little waived the age restriction from the Idaho Code §54-1704(5), which had an age limit of six years in it for independent prescribing of immunizations. In June, Executive Order 2020-13 was issued, which called upon agencies to file the necessary documents to make any suspended regulations under coronavirus disease 2019 (COVID-19) permanent through the legislative process. The Board is currently pursuing the legislative change.

Q. Is there an age limit on administration of immunizations in Idaho?

A. No, there is no patient age limit on the administration of immunizations in Idaho. Dating back to 2011 – when immunization rules first appeared in the law – until now, there has been no age limit listed for administration.

Q. Does the Board intend to discuss and provide guidance concerning Idaho's stance and the impact on practice in the state relating to the amendments issued by United States Department of Health and Human Services (HHS) to the Public Readiness and Emergency Preparedness Act regarding immunizations?

A. The amendments made by HHS do not affect Idaho since the age limit has been waived.

Q. During this flu season and additionally in anticipation of a COVID-19 vaccine, we are looking at utilizing our permanent curbside pharmacy parking spots to also provide flu immunizations. Is this acceptable?

A. This is acceptable with the expectation that the pharmacy still follows its protocols and procedures to ensure patient safety.

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National Pharmacy Compliance News

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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 Recommends Health Care Providers Discuss Naloxone With Patients Receiving Opioids, OUD Treatment

Recognizing the importance of discussing naloxone with patients receiving opioids or medications to treat opioid use disorder (OUD), Food and Drug Administration (FDA) recommends that health care providers include such discussions as a routine part of prescribing these medications. Further, the agency is requiring label changes to these medications to include this recommendation. The revised labels will encourage health care providers to discuss the availability of naloxone with patients and caregivers, both when beginning and renewing treatment. The labeling changes also suggest that providers prescribe naloxone to patients being prescribed opioids who are at increased risk of opioid overdose.

"Even during this global pandemic, we have continued to prioritize addressing the opioid crisis," said FDA Commissioner Stephen M. Hahn, MD, in a press release. "Today's action can help further raise awareness about this potentially life-saving treatment for individuals that may be at greater risk of an overdose and those in the community most likely to observe an overdose. We will use all available tools to address this crisis, and we know efforts to increase access to naloxone have the potential to put an important medicine for combatting opioid overdose and death in the hands of those who need it most – those at increased risk of opioid overdose and their friends and family."

The complete list of changes is available through an July 2020 Drug Safety Communication.

Proposed Rule to Require Electronic Submission of DEA Form 106

A proposed rule requiring accurate electronic submission of DEA Form 106 was published by Drug Enforcement Administration (DEA) in the *Federal Register* on July 29, 2020. The form, used by DEA registrants to report thefts or significant losses of controlled substances (CS), would also need to be submitted within a 15-day time period under the proposed rule. DEA registrants who experience theft or loss of CS would still be required to notify the DEA Field Division Office in their area, in writing, within one business day of discovery. According to the announcement published in the *Federal Register,* this requirement will impact the remaining 0.5% of DEA Form 106 responses that are reported by paper.

Inappropriate FentaNYL Patch Prescriptions at Discharge for Opioid-Naïve, Elderly Patients

This column was prepared by the Institute for Safe Medication Practices (ISMP), an ECRI affiliate. Have you experienced a medication error or close call? Report such incidents in confidence to ISMP's National Medication Errors Reporting Program online at www.ismp.org *or by email to ismpinfo@ismp.org to activate an alert system that reaches manufacturers, the medical community, and FDA. To read more about the risk-reduction strategies that you can put into practice today, subscribe to the ISMP Medication Safety Alert!® newsletters at* www.ismp.org.

ISMP recently heard from a long-term care (LTC) pharmacy about an increase in the prescribing of transdermal fenta**NYL** patches for elderly patients. In most cases, the pharmacists reviewing the patients' orders determined that the fenta**NYL** patches had been inappropriately prescribed for opioid-naïve patients, sometimes to treat acute pain rather than chronic pain. One of the more common underlying causes appears to be a knowledge deficit about the dangers of prescribing this opioid analgesic to opioid-naïve patients. Several of the events began in a hospital, with opioid-naïve patients receiving prescriptions for fenta**NYL** patches after treatment in an emergency department (ED) or upon discharge and transfer to a LTC facility. Prescribing a fenta**NYL** patch to elderly, opioid-naïve patients can result in fatal or life-threatening respiratory depression and overdose.

In one event, an 88-year-old resident from a LTC facility fell and was taken to a local hospital ED, where multiple rib fractures were diagnosed. Upon discharge

from the ED, the resident was prescribed a fenta**NYL** patch, 25 mcg/hour, every 72 hours. At the LTC facility, a consultant pharmacist reviewed the medication orders and the resident's medication history. The pharmacist determined that the resident had not received a prescription for opioids in the past year, revealing he was opioid-naïve. The consultant pharmacist contacted the prescribing ED physician to discuss the order for the fenta**NYL** patch. The ED physician reported that the resident had received "three small IV push doses" of fenta**NYL** in the ED, mistakenly believing this meant the resident was opioid-tolerant.

Additionally, the ED physician had prescribed the fenta**NYL** patch because the resident had a documented allergy to codeine. The ED physician mistakenly believed the fenta**NYL** patch was the only viable option. The consultant pharmacist clarified that the LTC records indicated that the resident had experienced mild nausea and an upset stomach while taking **HYDRO**codone and acetaminophen when he was younger, which is not an allergy but rather a mild intolerance. The ED physician changed the resident's analgesic to oral oxy**CODONE** 5 mg as needed every four to six hours.

Reliance on product labeling and practitioner education alone will not prevent life-threatening errors with fenta**NYL** patches. Yes, health care practitioners should be educated about safe prescribing, and their competency should be verified as a prerequisite to prescribing. But there will always be those who are unaware of the risks they take prescribing fenta**NYL** patches to opioid-naïve patients to treat acute pain. Thus, system safeguards must be established to avoid the risk of harm.

Fenta**NYL** patches should only be prescribed for patients who are opioid-tolerant with persistent, moderate-to-severe chronic pain that requires around-the-clock, long-term opioid administration. In 2018, ISMP called for the elimination of prescribing fenta**NYL** patches for opioid-naïve patients and/or patients with acute pain in our *Targeted Medication Safety Best Practices for Hospitals*. In 2020, this best practice was incorporated into a new best practice (No.15) to verify and document the patient's opioid status and type of pain before prescribing and dispensing extended-release opioids.

When entering discharge and transfer orders, interactive alerts requiring confirmation that the patient is opioid-tolerant and experiencing chronic pain might help prevent inappropriate prescribing, as might hard stops if patients do not meet prescribing criteria. Consider creating a daily list of discharge prescriptions and transfer orders for fenta**NYL** patches generated from the order entry system, and requiring a hospital pharmacist to review them to verify that the patient is opioid-tolerant and has chronic pain.

Engage patients. Educate all patients prescribed a fenta**NYL** patch and their caregivers about how to use the patch safely.

SAMHSA Health Privacy Rule Revised to Better Integrate, Coordinate Care for Patients With SUD

A revised Substance Abuse and Mental Health Services Administration (SAMHSA) rule will make it easier for people diagnosed with substance use disorders (SUDs) to receive integrated and coordinated care. The revisions to the agency's Confidentiality of Substance Use Disorder Patient Records regulation, 42 CFR Part 2, advances the integration of health care for individuals with SUDs while maintaining critical privacy and confidentiality protections.

According to a US Department of Health and Human Services (HHS) press release, under Part 2, a federally assisted SUD program may only disclose patient identifying information with the individual's written consent, as part of a court order, or under a few limited exceptions. In addition, health care providers, with patients' consent, will be able to more easily conduct quality improvement, claims management, patient safety, training, and program integrity efforts.

The revised rule modifies several major sections of Part 2, including provisions related to records, consent requirements, and research, among others. For a list of changes in the final rule, visit the HHS Fact Sheet.

HHS Assistant Secretary for Mental Health and Substance Use Elinore F. McCance-Katz, MD, PhD, the head of SAMHSA, further stated, "Modernizing 42 CFR Part 2 will strengthen the nation's efforts to reduce opioid misuse and abuse and to support patients and their families confronting substance use disorders. The rule will make it easier for primary care clinicians to treat individuals with substance use disorders."

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Q. Is it mandated that all technicians administer vaccines?

A. Administration of vaccines by technicians is not a mandate in Idaho, it is an opportunity. There may be pharmacies that choose not to delegate the task. There also may be pharmacies that choose only certain staff based on their own internal criteria or knowledge of that individual technician's skill and competency. This approach allows for flexibility and a common-sense approach to delegation in accordance with IDAPA Rule 24.36.01.100.

Q. Does the Board have any set standards on required education for technicians administering immunizations?

A. IDAPA 24.36.01.100 requires that the action being delegated to a technician be within the education, training, and practice experience of the person to whom the task is delegated. The Board has not selected a single program to accomplish this outcome. If a complaint were to be received, these elements would be given significant consideration as part of the investigation.

Pharmacist Prescribing of Naloxone to Be Reported Under Pharmacists' NPI Number

The Board is encouraged to see more pharmacists throughout Idaho recognizing patient need and prescribing naloxone. In the past, these prescriptions were required to be reported using only the pharmacy's Drug Enforcement Administration (DEA) number. The Idaho Prescription Drug Monitoring Program (PDMP) was recently updated to allow pharmacists to use their National Provider Identifier (NPI) number when prescribing. For reporting to the PDMP, use the prescribing pharmacist's NPI and the pharmacy's DEA number.

As additional practitioners come to serve Idahoans, the Board is seeing more and more individual practitioners have multiple DEA registrations. Yes, practitioners can have multiple DEA registrations as each registration is location specific. Data errors submitted to the PDMP cause additional work for the pharmacy and Board staff. Please be **extremely** cautious when selecting the provider for prescriptions to ensure that you have selected the correct provider and the correct location of that provider. If there is an error, the provider's DEA registration will need to be corrected and the information resubmitted to the PDMP's Clearinghouse. If you do not know how to submit a correction, contact your IT department.

Controlled Substance Sales by Pharmacies to Practitioners – For Office Use

Effective January 1, 2021, pharmacies that sell to practitioners for office use will be required to submit copies of DEA Form 222 or the invoice for Schedule III-V and legend drugs when reporting monthly sales. This change is due to the numerous errors listed on the spreadsheets that most wholesaling pharmacies use to report their practitioner sales. Invoice copies should be sent to bop.pmp@bop.idaho.gov no later than the 15th day of the month.

DEA Form 106 Submission Rules Considered

Proposed rulemaking relating to the reporting of theft or significant loss of controlled substances (CS) was published in the DEA *Federal Register* [Volume 85, Number 146, pages 45547-45551 (Wednesday, July 29, 2020)]. In summary, this proposed rule would amend DEA regulations regarding DEA Form 106, used by DEA registrants to report thefts or significant losses of CS, to clarify that all such forms must be submitted electronically. In addition, the proposed rule would add new requirements for the form to be submitted accurately and within a 15-day time period. This proposed rule will not change the requirement that registrants notify the DEA Field Division Office in their area, in writing, of the theft or significant loss of any CS within one business day of discovery of such loss or theft.

Naturopathic Medical Doctors Can Now Prescribe Testosterone

The recently formed Naturopathic Medical Board's proposed rules were passed in the legislature last spring. This board and its rules reside within the Idaho Board of Medicine structure. Naturopathic medical doctors (NMDs) can prescribe, dispense, administer, and order in accordance with the Naturopathic Medical Board's rules. Prescribing is defined by formulary and consists "of non-controlled legend medications excluding testosterone deemed appropriate for the primary health care of patients within the scope of practice and training of each naturopathic medical doctor." Testosterone prescribing is limited to "physiologic doses with regular lab assessment for hormone replacement therapy, gender dysphoria, or hypogonadism." To verify if a practitioner is a licensed NMD, please use License Search on the Board of Medicine's website.

Board Sets 2021 Meeting Schedule

Board meetings play an important role in the regulation of pharmacy practice in Idaho. The Board extends an open invitation to all pharmacists, technicians, student pharmacists, and other interested parties to attend and actively participate in these meetings. Your feedback and engagement can help ensure that public health and patient safety are optimized in our state.

All meetings will be held in Boise, ID, on the following dates in 2021:

- January 19
- March 18
- June 10 (negotiated rulemaking)
- July 8 (negotiated rulemaking)
- July 27 (negotiated rulemaking) – conference call
- August 26 (proposed rulemaking)
- October 28 (adoption of pending rules)

While these are open public meetings, seating capacity is limited due to the social distancing protocols implemented for the COVID-19 pandemic. The public is encouraged to attend telephonically. Please visit the Board's website for information prior to each meeting. There you will find meeting

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agendas, conference call numbers, minutes, and public meeting materials. The public meeting materials are typically available for download 48 hours prior to each meeting. Licensees or members of the public seeking to be on the agenda may contact the Board's executive director, Nicki Chopski, at Nicki .Chopski@bop.idaho.gov or 208/334-2356. The deadline to request to be on the agenda is posted for each meeting on the Board's website and is typically six weeks prior to the meeting date.

Facility Renewals Due December 31

As a reminder, courtesy renewal notices for facilities have been sent out to the email address of record. Please ensure that the facility license/registration is renewed before the end of the year. As part of the renewal process, please ensure that all contact information for the facility is current.

Per IDAPA 24.36.01.501.02, changes to information provided on or with the initial or renewal application must be reported to the Board within 10 days of the change. This includes email addresses. Failure to receive a courtesy reminder is not an acceptable reason to not renew a facility license/registration in a timely manner.

Help Is Available for Impaired Pharmacists Through Idaho PRN

The Board 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.

Special Notice

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

The *Idaho State Board of Pharmacy News* is published by the Idaho State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

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