JUNE 2022

IDAHO STATE BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

2021-2022 Summary of Pharmacy Administrative Rule Changes

Traditionally, the administrative rules are reauthorized at the conclusion of the legislative session. However, the 2021 legislative session ended without the reauthorization taking place. Governor Brad Little reauthorized the rules as temporary and proposed to ensure that existing administrative codes remained in effect. The following is a summary of the rule changes that became effective on July 1, 2021:

- IDAPA 24.36.01.213 – reduces confusion related to renewal being completely separated from the continuing pharmacy education requirement of 15 credits per year.
- IDAPA 24.36.01.302 – simplifies the requirements of drug outlets without an on-site pharmacist or prescriber. The Idaho State Board of Pharmacy simplified the technology storage requirements to 30 days, removed redundant security language, and made the rule consistent with the Idaho Telehealth Access Act.
- IDAPA 24.36.01.350 – simplifies the list of parameters related to the general requirements of pharmacist prescribing. Removes duplication and streamlines other elements.
- IDAPA 24.36.01.351 – streamlines the collaborative pharmacy practice rule.
- IDAPA 24.36.01.403 – following the beginning of the coronavirus disease 2019 (COVID-19) pandemic, the Board clarified adaptation included strength in the list of elements that can be adapted.

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- IDAPA 24.36.01.404 – also following the beginning of the COVID-19 pandemic, the Board again clarified "drug product substitution" and therapeutic interchange.
- IDAPA 24.36.01.406 – adds the second portion of the federal requirement to the labeling standards for distributed compounded drug products to remove confusion between state and federal law.

After two public meetings over the summer, an additional rule change was submitted to go pending before the legislature.

- IDAPA 24.36.01.220 to clarify that any student with a "high school equivalency diploma" may qualify for pharmacy technician registration, including those who are homeschooled or in an apprenticeship training model.

Rules posted in the October 2021 bulletin were presented to the 2022 legislature. Again, the 2022 legislative session ended without the necessary concurrent resolution taking place. The governor then reauthorized the rules as both temporary and proposed to ensure that existing administrative rules remain in effect as of March 31, 2022. A full copy is posted in the June administrative bulletin.

Department of Health and Welfare Expansion of Idaho Resource Tracking System to Include Pharmacies

The Idaho Department of Health and Welfare (DHW) is expanding its Idaho Resource Tracking System (IRTS) to include pharmacies across the state of Idaho. In the past, local public health districts and DHW communicated directly with pharmacies about antiviral availability, such as Tamiflu® and Relenza® as influenza season kicks off in the fall, for two reasons:

1) to build relationships with the pharmacies before a public health emergency, and

2) to provide antiviral inventory situational awareness information to the state medical director.

As we have learned from the COVID-19 pandemic, it is imperative to receive timely updates; therefore, DHW has expanded its reporting system and found it highly effective for monoclonal antibodies (mAbs) inventory tracking to submit orders on a weekly basis for Idaho hospitals. During the pandemic, the DHW information platform was extended to incorporate hospitals and long-term care facilities not only to track mAbs and antivirals for COVID-19, but also for personal protective equipment daily burn rates and hospital surge capacity. It has proven itself to be a great tool for decision making.

What does this mean going forward? To streamline this process, DHW will be using the IRTS to collectively acquire the availability of various medications used during a public health emergency. DHW will be reaching out to gather critical information such as primary contact information. DHW will provide training and instructions on how the system works once your account is created and ask you to take part in two drills every year, so everyone is prepared for a real-world incident.

With your help, DHW can maintain a more robust and comprehensive resource tracking tool for pharmaceuticals to help fellow Idahoans during the next public health emergency.

For more information, please reach out to Jodi.Fulbright@dhw.idaho.gov.

Culture of Safety – Recent Medication Errors Reported

In hopes that all may learn from the experience of others and look for ways to increase safety and decrease errors, the Board is sharing the following medication error events that occurred over the last few months. The processes implemented to instill improvements are also shared.

Error 1

Synopsis (wrong drug): A patient presented with a prescription for morphine sulfate 15 mg extended release but was given morphine sulfate 15 mg immediate release instead. The pharmacist did not identify the mistake and dispensed the incorrect medication.

Outcome: The drug outlet agreed to:

- Institute policies and procedures for an in-house quality assurance reporting plan
- Conduct a quarterly quality assurance reporting plan with staff
- Establish proper counseling procedures since they would have likely prevented the incident

Error 2

Synopsis (wrong dose): A patient was given prednisone 20 mg instead of the prescribed prednisone 100 mg. The pharmacist did not identify the mistake and dispensed the incorrect medication.

Outcome: The licensee agreed to:

- Complete 18 credit hours of continuing education using Oregon State University's Patient Safety and Medication Error Prevention for Pharmacy course
- Complete a quality assurance assessment

Error 3

Synopsis (wrong patient): When a patient was picking up multiple prescriptions for herself, she was also given a prescription for a different patient. She was asked for identification due to the wrong patient's prescription being a controlled substance (CS). The patient questioned the reason for this procedure since it had not happened before, but discovery of the incident was not made until the patient returned home.

Outcome: The drug outlet agreed to:

- Institute policies and procedures for an in-house quality assurance reporting plan
- Conduct a quarterly quality assurance reporting plan with staff
- Verify each medication at the register with the patient if they have multiple prescriptions

- Make a good effort to locate a medication if a prescription shows it was filled
    - Staff must also be made aware to look for lost medication when dispensing other prescriptions

Error 4

Synopsis (wrong drug): A complaint regarding a medication error was received by the Board. A prescription was dispensed with clomipramine 50 mg in place of the correct medication of clomiphene citrate 50 mg. The staff did not identify the mistake and dispensed the incorrect medication.

Outcome: The drug outlet agreed to:

- Provide a process improvement plan with written policy and procedures that will be followed by all staff that specifically addresses each part of the process and the actions of parties that contributed to the error

Error 5

Synopsis (wrong drug): A patient was given dextroamphetamine/amphetamine extended-release instead of the prescribed dexmethylphenidate extended-release 15 mg. The staff did not identify the mistake and dispensed the incorrect medication. The facility took action to correct the matter.

Outcome: The drug outlet agreed to:

- Submit a copy of the official action plans mentioned in response to the investigatory letter
- Provide an additional process improvement plan with written policy and procedures that will be followed by all staff, which specifically addresses each part of the filling process

Annual CS Inventories Frequent Source of Noncompliance

Because of a recent uptick in noncompliance, the Board is reminding registrants of the annual CS inventory requirements. IDAPA 24.36.01.500.03 states:

> **Inventory Records.** Each drug outlet must maintain a current, complete and accurate record of each controlled substance manufactured, imported, received, ordered, sold, delivered, exported, dispensed or otherwise disposed of by the registrant. Drug outlets must maintain inventories and records in accordance with federal law. An annual inventory must be conducted at each registered location no later than seven (7) days after the date of the most recent inventory in a form and manner that satisfies the inventory requirements of federal law. Drugs stored outside a drug outlet in accordance with these rules must be regularly inventoried and inspected to ensure that they are properly stored, secured, and accounted for. Additional inventories are necessary when required by federal law.

Federal law states that an "inventory" is a complete and accurate list of all stocks and forms of CS in the possession of the registrant as determined by an actual physical count for Schedule II drugs. With respect to inventories of Schedule III-V drugs, the registrant may, with respect to an open bottle that contains no more than 1,000 tablets, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules, in which case an exact count of the contents must be made. See 21 Code of Federal Regulations (CFR) 1304.11(e)(6)(i) and (ii).

In addition, the inventory records of Schedule II CS must be kept separate from all other records of the drug outlet. The inventory records of Schedule III-V CS must be maintained either separately from all other records of the drug outlet or in such form that the information required is readily retrievable from ordinary business records of the drug outlet. Under 21 CFR Part 1300, the inventory shall include:

1. The date of the inventory
2. Whether the inventory was taken at the beginning or close of business
3. The name of each CS inventoried
4. The finished form of each of the substances (eg, 10 mg tablet)
5. The number of dosage units or volume of each finished form in the commercial container (eg, 100 tablet bottle or three mL vial)
6. The number of commercial containers of each finished form (eg, four 100 tablet bottles)
7. The total on-hand count of the substance

Although it is not required by law, Drug Enforcement Administration (DEA) recommends that registrants keep an inventory record that includes the name, address, and DEA registration number of the registrant, as well as the signature of the person or persons responsible for taking the inventory. Neither white-out nor negative numbers should appear in the CS inventory.

Prevent Injection-Related Harm With Safer Syringe Access

By Randi Pedersen, MPH, Syringe Exchange Program Manager at Idaho Department of Health and Welfare, Division of Public Health; and Dawn Berheim, PharmD, RPh, Pharmacist at Idaho Department of Health and Welfare, Division of Medicaid

Nearly all injection-related harm is preventable. Lack of access to sterile needles and syringes to safely inject medicine, such as insulin, increases the likelihood that people will share or reuse injection supplies, raising the risk for injection-related harms such as viral hepatitis, HIV, and injection-site infections. In Idaho, licensed pharmacists have an opportunity to help prevent injection-related harm by providing sterile syringes and needles when requested, improving safer syringe access statewide. Pharmacists are encouraged to err on the side of caution and provide safer syringe access when requested since the inability to obtain insulin injection supplies can create a life-threatening emergency for a diabetic or prompt unsafe injection behaviors that increase harm.

In 2019, the Syringe and Needle Exchange Act (Idaho Code §37-3401) was passed by the Idaho Legislature providing another opportunity for safer syringe access through community-based organizations. Idaho's eight Safer Syringe Program (SSP) locations serve anyone who needs safer injection supplies for a medical condition or substance use disorder (SUD) without judgment or stigma. Idaho SSPs also provide low-barrier, wraparound services that include HIV and viral hepatitis testing, wound care, vaccines, naloxone, social services, and recovery support for people with SUDs, among others. To find an SSP near you or to connect a patient, visit *findidahotesting.com.*

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.

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