SEPTEMBER 2023

IDAHO DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSES

newsletter to promote pharmacy and drug law compliance

Board Elects New Chairperson

Justin Messenger, PharmD, was elected chair at the June 8, 2023, Idaho State Board of Pharmacy meeting. Dr Messenger is a hospital pharmacist from southeast Idaho.

Message From the Board Chair

The Board acknowledges that changes in the education and training of pharmacists, as well as rapid advancements in the technological environment, have required a change in approach to regulating the practice of pharmacy. The Board continues to embrace those changes and the growth of our profession.

Board Rule IDAPA 24.36.01.100 provides guidance to licensees and registrants as they determine whether a specific act is permissible. First, a licensee or registrant should consider whether the act is expressly prohibited by any state or federal law. If an act is not expressly prohibited, the licensee should consider whether:

- the act is consistent with the licensee or registrant's education, training, or practice experience; **and**
- performance of the act is within the accepted standard of care that would be provided in a similar setting by a reasonable and prudent licensee or registrant with similar education, training, and experience.

Two questions that may help licensees or registrants successfully navigate this change in approach from prescriptive rules to professional judgment follow:

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1. If someone asks why I made this decision, can I justify it as being consistent with good patient care and with law?
2. Would this decision withstand a test of reasonableness (eg, would another prudent pharmacist make the same decision in this situation)?

You should consult an attorney if you have questions as to the legality of your actions under the laws and rules regulating pharmacy in the state of Idaho. It is your responsibility to ensure that you are acting consistently with those laws and rules.

Prescribing Pharmacists

The administrative rule **350. Pharmacist Prescribing: General Requirements** was recently revised during the last legislative session. Please review the general requirements:

> In accordance with Section 54-1705, Idaho Code, a pharmacist may independently prescribe provided the following general requirements are met by the pharmacist:
>
> **01. Education.** Only prescribe drugs or devices for conditions for which the pharmacist is educationally prepared and for which competence has been achieved and maintained.
>
> **02. Patient-Prescriber Relationship.** Only issue a prescription for a legitimate medical purpose arising from a patient-prescriber relationship as defined in Section 54-1733, Idaho Code.
>
> **03. Patient Assessment.** Obtain adequate information about the patient's health status to make appropriate decisions based on the applicable standard of care and the best available evidence.
>
> **04. Collaboration with Other Health Care Professionals.** Recognize the limits of the pharmacist's own knowledge and experience and consult with and refer to other health care professionals as appropriate.
>
> **05. Documentation.** Maintain documentation adequate to justify the care provided including, but not limited to, the information collected as part of the patient assessment, the prescription record, provider notification, and the follow-up care plan.

06. Prescribing Exemption. The general requirements set forth in this section do not apply to collaborative pharmacy practice agreements, devices, and nonprescription drugs.

All practitioners, including pharmacists, who are practicing in or into Idaho and prescribe controlled substances (CS) are required to obtain a separate CS registration and are subject to compliance with all requirements under Title 37, Chapter 27, Idaho Code and federal law. Visit Idaho Practitioner Controlled Substance Registration (CSR) to register. The Idaho CSR is required for those who will **prescribe, administer, order, or store CS.** Per Idaho law, once the Idaho CSR is issued, an associated Drug Enforcement Administration (DEA) registration must be obtained for that Idaho address within 45 days, either as a new DEA registration or by moving an existing DEA registration to the Idaho address.

Once issued a primary Idaho CSR, any additional Idaho practice address requires a separate Idaho CSR and associated DEA registration **only if** the practitioner will be **administering, ordering, or storing CS** at the additional address.

Reminder to dispensers: Specified data on CS must be reported to the Idaho Prescription Drug Monitoring Program by the **end of the next business day** by all drug outlets that dispense CS in or into Idaho and by prescribers who dispense CS to humans.

DEA Publishes Rule for Transfer of Electronic Prescriptions for Schedule II-V CS Between Pharmacies for Initial Filling

On July 27, 2023, DEA amended its regulations to allow the transfer of electronic prescriptions for Schedule II-V CS between registered retail pharmacies for initial filling, upon request from the patient, on a one-time basis. This amendment specifies the procedure that must be followed and the information that must be documented when transferring such electronic CS prescriptions between DEA-registered retail pharmacies. This rule became effective on August 28, 2023.
The final rule specifies that: the transfer must be communicated directly between two licensed pharmacists; the prescription must be transferred in its electronic form and may not be converted to another form (eg, facsimile) for transmission; the required prescription information must be unaltered during the transmission; and the transfer of electronic prescriptions for CS for initial dispensing is permissible only if allowable under existing state or other applicable law. In addition to the above, the pharmacist transferring the prescription must update the electronic prescription record to note that the prescription was transferred. The transferring pharmacist must also record the name, address, and DEA registration number of the pharmacy to which the prescription was transferred, the name of the pharmacist receiving the transfer, the name of the transferring pharmacist, and the date of the transfer. Similarly, the pharmacist receiving the transferred prescription must record the transferring pharmacy's name, address, and DEA registration number, the name of the transferring pharmacist, the date of the transfer, and the name of the pharmacist

receiving the transfer. Finally, the final rule requires that the electronic records documenting the transfer be maintained for a period of two years from the date of the transfer by both the pharmacy transferring the electronic prescription and the pharmacy receiving the prescription.

The full draft document can be accessed here.

FDA Provides Updated Drug Shortage and Compounding Information for Medications Containing Semaglutide Marketed for Type 2 Diabetes or Weight Loss

The Board received the following information from Food and Drug Administration (FDA) through the National Association of Boards of Pharmacy®:

FDA has provided updated information about FDA-approved semaglutide products, which are marketed for type 2 diabetes or weight loss, and its concerns about compounding semaglutide products. Semaglutide is a glucagon-like peptide-1 receptor agonist, and there are currently three FDA-approved semaglutide products: Ozempic® injection, Rybelsus® tablets, and Wegovy® injection. These three medications are available by prescription only, and there are no approved generic versions. As of May 2023, Ozempic and Wegovy are on FDA's Drug Shortages List, which may allow compounders to prepare a compounded version of these drugs if they meet certain requirements in the Federal Food, Drug, and Cosmetic Act (FD&C Act). The active pharmaceutical ingredient in Ozempic and Wegovy is semaglutide in its base form. FDA is aware, however, that in some cases, compounders may be using salt forms of semaglutide, including semaglutide sodium and semaglutide acetate. The salt forms are different active ingredients than what is used in the approved drugs. FDA is not aware of any basis for compounding using the salt forms that would meet the FD&C Act's requirements for types of active ingredients that can be compounded. FDA has received adverse event reports after patients used compounded semaglutide. Health care professionals and patients should understand that FDA does not review compounded versions of these drugs for safety, effectiveness, or quality, and are reminded to not use a compounded drug if an approved drug is available. FDA encourages health care professionals, compounders, and patients to report adverse events or quality problems to its MedWatch Adverse Event Reporting Program.

The full semaglutide update may be viewed here.

Navigating the New Website

Here are some tips for navigating the Board's new website, which was recently restructured.

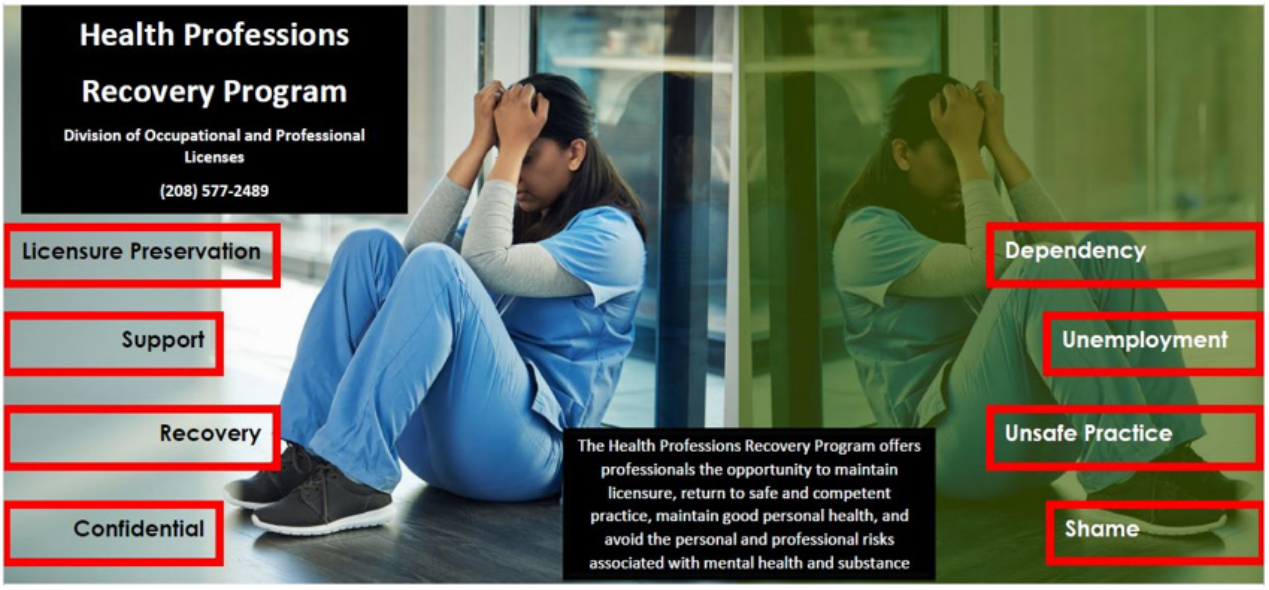
To access the licensing portal from the Board's main page:

1. Click "Apply for or Renew a License."
2. At the top of the page, click "online licensing portal (egov)."

To update an employee roster for a resident drug outlet:

1. From the Board home page, click the “Update Contact Information” button.
2. Click “Resident Drug Outlet Employee Roster Update.”
3. Click *e-gov.com.*
4. Log in to the facility account that needs to be updated.
5. Click on “update license.”
6. Update employee roster and save changes.

Reminder: Mozilla Firefox is **not** a compatible browser with the licensing portal at this time. Please use Microsoft Edge, Google Chrome, or Safari to access the licensing portal.



Health Professional Recovery Program

Are you working long hours and feeling burned out?

Do you feel yourself going down the wrong path?

Are you ready to make changes?

You can choose the direction you are going and get help with substance use or mental health.

The Idaho Division of Occupational and Professional Licenses offers a confidential, nonpunitive program. This program was created to assist medical professionals (doctors, nurses, dentists, pharmacists, etc) who have or are at risk of developing an addiction. The program’s purpose is to assist professionals and their families to identify substance use disorders that pose a potential threat to their careers and get them the help they need.

If you answered yes to any of the questions above, let us help you preserve your license and get you on the road to recovery. For further information about this program, contact Katie Stuart.

Program Manager: Katie Stuart, CIP
Phone: 208/577-2489
Email: Katie.Stuart@dopl.idaho.gov
Website: Welcome to Division of Occupational and Professional Licenses (idaho.gov)

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