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News

Nevada State Board of Pharmacy

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New Online Renewal Process

By Kristopher Mangosing

Pharmacist licenses are due for renewal by October 31, 2019. The Nevada State Board of Pharmacy has a new renewal process. The Board has contracted with inLumon to create a user-friendly, flexible, and secure way to renew your license online. Pharmacists will be receiving both an emailed and a mailed reminder to renew. The option to renew by mail is still available, but the Board encourages pharmacists to renew online to save time and money.

For many, this will be the first time logging in to the Board's new online renewal site. The first time you access the site, you will need to register. The registration process is short and straightforward. Please remember to keep your login information secure. Follow the prompts to register and log in to your dashboard. This will provide Board staff with current and accurate contact information to communicate with licensees and will grant you access to your dashboard. In the future, you will use this portal as a means to complete additional licensing activities and communicate with Board staff.

From the dashboard, you will be able to renew your license online and view and/or print your receipt and certificate. When renewing online, you will be able to answer all required questions and upload any supplemental documentation. Licensees will have the ability to pay for their renewal with a debit or credit card, regardless of what method they choose to renew. Once your renewal

has been submitted and processed by Board staff, you will receive an email with your receipt and your certificate. As part of the Board's "green" and cost-saving initiatives, Board staff will no longer mail out physical copies of certificates. Please refer to your email or log back in to your dashboard to print a copy for your records. Be sure to provide Board staff with a current email address that you check regularly. Your email and dashboard will become the primary methods of communication with Board staff.

One-Hour Nevada Law CE Requirement

Pharmacists, before you renew your pharmacist license with the Board, you must complete 30 hours of continuing education (CE) within the biennium immediately preceding the current renewal period. One of the CE hours must be Nevada law CE.

If you have not already completed your one hour of Nevada law CE, you may now do so for **free** online. Visit <http://bop.nv.gov/services/CE> and successfully complete the requirements to obtain your one hour of Nevada law CE. Please maintain any certification as your record.

You are exempted from the one-hour Nevada law CE requirement if you are:

1. a new graduate – this exemption is good for two years after you receive your degree in pharmacy; or
2. an applicant who is residing and practicing outside of Nevada.

The regulations relevant to this topic are Nevada Administrative Code (NAC) 639.330 and NAC 639.335.

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National Pharmacy Compliance News

October 2019



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.

NABPF

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USP Postpones Official Dates of USP General Chapters Revisions and Additions

United States Pharmacopeial Convention (USP) has announced that the effective date of the following changes to USP general chapters will be postponed:

- ◆ [General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations](#)
- ◆ [General Chapter <797> Pharmaceutical Compounding – Sterile Preparations](#)
- ◆ [General Chapter <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging](#)

The delay is in accordance with USP's Bylaws, which require the official date of the standard to be postponed while an appeal is pending. In the meantime, conformance with the official versions of [Chapters <795> and <797>](#), including the section "Radiopharmaceuticals as CSPs," will remain official, according to a [notice](#) posted to the USP website.

Revisions to USP [General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings](#) are not subject to pending appeals, and will become official on December 1, 2019. During this interim period, Chapter <800> is "informational and not compendially applicable," according to the USP notice. However, the organization encourages utilization of the chapter in the interest of advancing public health. USP also notes that it plays no role in enforcement and that regulators continue to have the authority to make their own determinations regarding enforceability of Chapter <800>.

FDA Issues Statement on Compounded Bulk Drug Substances Ruling

A US district court judge in Washington, DC, recently upheld Food and Drug Administration's (FDA's) interpretation of clinical need regarding bulk substances that may be used by outsourcing facilities in drug compounding. In response to the ruling, FDA has released a statement commending the decision as a "victory for public health in the first such case since the Drug Quality and Security Act (DQSA) was enacted."

In March 2019, FDA announced that vasopressin would not be included as an approved bulk drug substance because there is already an approved product on the market to meet the same medical needs. The ruling was in response to a challenge of that interpretation. In their statement, the agency states that they will continue to evaluate bulk drug substances nominated for use in compounding by outsourcing facilities using the same interpretation of clinical need.

"Our compounding work remains a top priority at the agency. We've long recognized that compounded drugs can serve an important role for patients whose medical needs cannot be met by an FDA-approved drug product," the agency states. "But compounded drugs are not approved by the FDA and, therefore, have not been evaluated for safety, efficacy or quality. We've seen first-hand the harm they can cause patients when they're not appropriately compounded."

HHS, FDA Publish New Action Plan for Importation of Certain Prescription Drugs

The US Department of Health and Human Services (HHS) and FDA have published a Safe Importation Action Plan to allow for the safe importation of certain drugs originally intended for foreign markets. The action plan outlines two possible pathways:

- ◆ **Pathway 1** would rely on the authority in the Federal Food, Drug, and Cosmetic Act Section 804 to authorize demonstration projects to allow importation of drugs from Canada. The proposed rules would include conditions to ensure the importation poses no additional risk to consumers and must result in a significant cost reduction.
- ◆ **Pathway 2** would allow manufacturers to import versions of FDA-approved drug products that they sell in foreign countries that are the same as the US versions. Manufacturers would use a new National Drug Code for those products, potentially allowing them to offer a lower price than what their current distribution contracts require.

The action plan states that the final proposal for these rules may differ from the descriptions "to reflect further consideration of the relevant issues."

"Today's proposal is the result of the hard work by the dedicated staff of the FDA, in close collaboration with HHS and the White House, to identify potential pathways we can pursue to support the safe importation of certain prescription drugs," said Acting FDA Commissioner Ned Sharpless, MD in a press release. "We've been keenly focused on ensuring the importation approaches we've outlined pose no additional risk to the public's health and safety. We know there are many operational challenges to address through each of these pathways, and are actively working through them as we look to formally announce these policies, with opportunity for public comment, in the coming months."

The full action plan can be accessed via the HHS website at <https://www.hhs.gov/sites/default/files/safe-importation-action-plan.pdf>.

Pain Reliever Misuse Decreased by 11% in 2018, NSDUH Survey Indicates

Prescription drug misuse, including abuse of stimulants and pain relievers, decreased in 2018, according to the recently released 2018 National Survey on Drug Use and Health (NSDUH). The annual survey, conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA), a division of HHS, is a primary resource for data on mental health and substance use, including abuse of prescription drugs, among Americans.

Key findings of the 2018 NSDUH include:

- ◆ Past-year abuse of psychotherapeutics decreased from 6.6 from 6.2%.
- ◆ Past-year abuse of pain relievers decreased from 4.1% to 3.6%.
- ◆ Past-year abuse of stimulants decreased from 2.1% to 1.9%.
- ◆ Past-year abuse of opioids decreased from 4.2% to 3.7%.

“This year’s National Survey on Drug Use and Health contains very encouraging news: The number of Americans misusing pain relievers dropped substantially, and fewer young adults are abusing heroin and other substances,” said HHS Secretary Alex Azar. “At the same time, many challenges remain, with millions of Americans not receiving treatment they need for substance abuse and mental illness. Connecting Americans to evidence-based treatment, grounded in the best science we have, is and will remain a priority for President Donald Trump, for HHS, and for SAMHSA under Assistant Secretary Elinore McCance-Katz.”

A recorded presentation of the data, along with a written summary and the full report are available on the SAMHSA website at <https://www.samhsa.gov/data/nsduh/reports-detailed-tables-2018-NSDUH>.

Additional Efforts Needed to Improve Naloxone Access, CDC Says

A new Vital Signs report published by the Centers for Disease Control and Prevention (CDC) states that naloxone dispensing has grown dramatically since 2012, with rates of naloxone prescriptions dispensed more than doubling from 2017 to 2018 alone. However, the rate of naloxone dispensed per high-dose opioid dispensed remains low, with just one naloxone prescription dispensed for every 69 high-dose opioid prescriptions.

The researchers for the report examined dispensing data from IQVIA, a health care, data science, and technology

company that maintains information on prescriptions from 50,400 retail pharmacies, representing 92% of all prescriptions in the US. According to their analysis, dispensing rates were higher for female recipients than for male recipients, and higher for persons aged 60-64 years than for any other age group. The researchers also found that the rate of naloxone prescriptions dispensed varied substantially across US counties, with rural and micropolitan counties more likely to have a low-dispensing rate.

“Comprehensively addressing the opioid overdose epidemic will require efforts to improve naloxone access and distribution in tandem with efforts to prevent initiation of opioid misuse, improve opioid prescribing, implement harm reduction strategies, promote linkage to medications for opioid use disorder treatment, and enhance public health and public safety partnerships,” the report states in its conclusion. “Distribution of naloxone is a critical component of the public health response to the opioid overdose epidemic.”

The Vital Signs report can be accessed at www.cdc.gov/mmwr/volumes/68/wr/mm6831e1.htm.

Altaire Pharmaceuticals Recalls Multiple OTC Ophthalmic Products

Due to a lack of sterility assurance, Altaire Pharmaceuticals, Inc, is voluntarily recalling over-the-counter (OTC) drug products and lots sold as generic ophthalmic medications at Walgreens, Walmart, CVS, and other retail pharmacies. To date, there have been no reports of adverse events related to the recalled products.

A full list of the affected products and lot numbers, as well as instructions on how to return the product, are available through the following press releases:

- ◆ Altaire Pharmaceuticals, Inc. Issues Voluntary Recall Of Multiple Ophthalmic Products Sold At CVS
- ◆ Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products Sold at Wal Mart
- ◆ Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products Sold at Walgreens
- ◆ Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products

Adverse reactions or quality problems experienced with the use of this product may be reported to FDA’s MedWatch Adverse Event Reporting program.