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News

Idaho State Board of Pharmacy

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No Restrictions in Place for Hydroxychloroquine Dispensing

As hydroxychloroquine continues to be in the coronavirus disease 2019 (COVID-19) pandemic headlines, the Idaho State Board of Pharmacy receives several calls each week regarding its status. At its June 2020 meeting, the Board reviewed Rule 704, which was in place to prevent stockpiling of medication, thereby preserving the supply chain. Following its review, the Board rescinded the rule, which had been in place since March 19, 2020. Because the supply of medication is stabilizing, it was determined that the rule was no longer needed. This change was published in the July 1, 2020 administrative bulletin.

Streamlining Licensing: Transition to Idaho Division of Occupational and Professional Licenses

After the implementation of Executive Order 2017-06 by then-acting Governor Brad Little, it was noted by the Licensing Freedom Act report that more than 200,000 licensees were permitted by multiple agencies, boards, and commissions. On March 11, 2020, the Idaho Legislature passed House Bill 318, giving authority to place self-governing agencies, like the Board, into an umbrella agency. Previously named the Bureau of Occupational Licenses, the new Idaho Division of Occupational and Professional Licenses (IDOPL) will provide the framework for licensing consistency and optimizing efficiencies.

On June 3, 2020, Governor Little signed Executive Order 2020-10, integrating 11 additional self-governing agencies into IDOPL and organizing the agencies into three categories:

1. Building, Construction, and Real Estate
2. Occupational Licensing
3. Health Professions

Appointed by the governor, the division administrator, among other duties, will oversee each section and its agencies therein. Each category will be led by a section chief, appointed by the division administrator, who is responsible for each agency within one of the three categories. Nicki Chopski, PharmD, BCGP, ANP, executive director of the Board, accepted the additional role as the section chief for Health Professions.

Since the development and implementation of the division set in motion by Governor Little, the Division has begun working toward the goal to streamline licensing among agencies. Additionally, the section chiefs are diligently striving to find alignment between agencies within their sections to promote consistency. Related to pharmacy, the Uniform Controlled Substances Act, under Title 37, Chapter 27, is being reviewed to be placed at the Health Professions section level. With continued efforts, the new arrangement of the Division will deliver uniformity and flexibility to licensing, budgeting, strategic planning, and legislative actions, which sets the foundation for the success of the Division and its goals.

Pharmacies to Assist With COVID-19 Screening

As the Idaho coronavirus team, led by the Department of Health and Welfare, continues its efforts to ramp up testing across the state, the Board has been given $3 million by the Coronavirus Financial Advisory Committee to award grants to assist pharmacies in setting up COVID-19 testing. Although the focus is toward pharmacies in rural areas of Idaho, pharmacists and pharmacies across the state are preparing to engage in testing. The grant money to pharmacies is earmarked to provide essential testing materials and equipment for point-of-care testing (POCT) and collection site testing.

The Idaho Pharmacy Leadership Council (IPLC) recently conducted a survey of Idaho pharmacists related to COVID-19 testing. The results of the survey identified several barriers that challenge pharmacies' abilities to provide POCT or collection site testing. The initial barriers to providing testing services are:

1. payment for services via medical insurance;
2. delays in lab testing with national lab partners; and
3. access to personal protective equipment (PPE).

The IPLC is collaborating closely with Medicaid to get the correct coding activated to allow pharmacists to bill for testing services, among which is the COVID-19 test. It is notable that Medicaid now legally recognizes pharmacists as providers and is in the process of establishing the correct codes in which pharmacies may utilize medical billing for services provided, similar to that of a physician assistant or advanced practice nurse. In the meantime, central funding from the awarded grant could serve as a temporary solution for billing.

Additionally, the Idaho Office of Emergency Management (IOEM) is working with local health districts to provide PPE to other health care professionals. As a foreseen limitation to pharmacy

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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 Releases MOU on Human Drug Compounding Regulation and Oversight

Acknowledging the vital role states play in reducing the risks associated with compounded drugs, Food and Drug Administration (FDA) has made available a Final Standard Memorandum of Understanding (MOU) Addressing Certain Distributions of Compounded Human Drug Products, intended to be entered into between the agency and the states. The release of the MOU is required as part of its submission to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act of 1995. The MOU was developed in close consultation with the National Association of Boards of Pharmacy® (NABP®), as described in the Federal Food, Drug, and Cosmetic Act. The agency also engaged with states, pharmacies, associations, pharmacists, and other stakeholders.

Among the issues addressed in the MOU is the definition of the statutory term "inordinate amounts," which refers to compounded drugs that are distributed interstate. In addition, the MOU includes the risk-based oversight model from the 2018 revised draft MOU. States that sign the document agree to identify pharmacy compounders that distribute inordinate amounts (greater than 50%) of compounded drug products interstate, as well as report certain information to FDA about those compounders. FDA also provided clarity in the MOU on state investigations of complaints associated with compounded drugs distributed out of state. States that enter into the MOU will investigate complaints about drugs compounded at a pharmacy within their state and distributed outside of the state and advise FDA when they receive reports of serious adverse drug experiences or serious product quality issues, like drug contamination.

To help states to better investigate these issues, FDA has also announced an agreement with NABP to make an information sharing network available to the states. Through this network, states will be able to obtain information from pharmacies in their states and transmit that information to FDA.

"We anticipate the final MOU, once signed, will help to facilitate increased collaboration between the FDA and the states that sign it," said Janet Woodcock, MD, Director, Center for Drug Evaluation and Research, in an FDA Voices article. "Working together, we can help promote quality compounding practices and better address emerging public health concerns that may affect patients."

FDA Clarifies Compounding Rules, Offers Flexibility to Help Ease Drug Shortages During COVID-19 Pandemic

FDA noted it will use discretion in enforcing certain standards related to 503A and 503B compounding in an effort to ease drug shortages during the coronavirus disease 2019 (COVID-19) pandemic. During an American Pharmacists Association (APhA) webinar on April 30, 2020, the agency clarified it will "look to 503B compounders to grapple with drug shortages" and "turn to 503A compounders to fill in the gaps."

In addition, the agency clarified that medications on the FDA drug shortage list are effectively considered "not commercially available," which frees 503A and 503B compounding facilities from limits on compounding drugs that are "essentially a copy" of a product already available on the market. FDA also does not intend to take action if a 503A facility fills orders for a compounded drug that is essentially a copy of an approved drug that has been discontinued and is no longer marketed.

In April 2020, FDA issued a temporary guidance that granted flexibility for pharmacists to compound certain necessary medications under 503A for nonspecific patients hospitalized due to COVID-19. In addition, a temporary guidance was issued that granted enforcement flexibility for 503B outsourcing compounding facilities for drugs in shortage for patients hospitalized during the COVID-19 public health emergency. The guidance documents stipulate the conditions compounders must meet and are available at *https://www.fda.gov/media/137125/download.*

More information on these compounding rule clarifications is available in a May 5, 2020 press release on the APhA website.

CMS Allows Pharmacies to Temporarily Enroll as Clinical Diagnostic Laboratories for COVID-19 Testing

Centers for Medicare & Medicaid Services (CMS) has released a document detailing a process that allows pharmacies to temporarily enroll as independent clinical diagnostic laboratories. This process will allow those

facilities to seek Medicare reimbursement for COVID-19 tests, making it easier for them to provide that service during the pandemic.

"Up until this point in time, most pharmacies could only offer this as a cash service because they were not considered providers through CMS, and really a lot of the third-party payers really didn't have an interest in a fee-for-service type model," said Michael E. Klepser, PharmD, FCCP, pharmacy professor at Ferris State University, in an interview with *Bloomberg Law.* "The fact that CMS is saying we're now authorizing or allowing pharmacists to get reimbursed for these is a great door opening at the federal level and that's a huge, huge thing."

Chain pharmacies such as CVS, Walgreens, and Rite Aid are offering drive-through testing at many pharmacies throughout the country.

FDA Issues Updated Guidance for Compounding Pharmacies Experiencing PPE Shortages

FDA has issued an update for its guidance to pharmacy compounders that may experience shortages of personal protective equipment (PPE) during the COVID-19 pandemic. As compounders typically utilize PPE when performing sterile compounding, the updated guidance clarifies that the drugs can be compounded under the policy in a segregated compounding area that is not in a cleanroom. This policy has been adopted to ensure patients continue to have access to medicines they need during the pandemic, and to reduce the risks of compounding when standard PPE is not available.

In addition to FDA guidance, United States Pharmacopeial Convention has previously issued an informational document for compounders regarding garb and PPE shortages during the pandemic. The document includes recommendations for conserving garb and PPE and what steps might be considered in the case of shortages of garb and PPE used for both sterile and nonsterile compounding.

The updated guidance can be accessed through FDA's website by visiting *www.fda.gov/media/136841/download.*

HHS Expands Telehealth Access in Response to COVID-19

In an effort to prevent and respond to the COVID-19 pandemic, the US Department of Health and Human Services (HHS) has awarded $20 million to increase telehealth access and infrastructure for health care providers and families. The funds, which are awarded through the Health Resources and Services Administration (HRSA), will increase capability; capacity and access to telehealth and distant care services for providers, pregnant women, children, adolescents, and families; and assist telehealth providers with cross-state licensure.

"This new funding will help expand telehealth infrastructure that is already being used during the pandemic to provide essential care, especially to the most vulnerable, including pregnant women and children with special health care needs," said HHS Secretary Alex Azar in a press release. "This funding will also help clinicians use telehealth nationally by streamlining the process to obtain multi-state licensure."

HRSA's Maternal and Child Health Bureau awarded a total of $15 million to four recipients; each award supports a key area in maternal and child health, including pediatric care, maternal health care, state public health systems, and family engagement for children with special health care needs. HRSA's Federal Office of Rural Health Policy awarded a total of $5 million to two recipients through the Licensure Portability Grant Program, which will assist telehealth clinicians nationally on licensure and credentialing to meet emerging needs related to COVID-19.

Criminals Found Posing as CDC Representatives to Steal Money and Information

Centers for Disease Control and Prevention (CDC) is warning the general public of a new type of phone and phishing scam by criminals posing as CDC representatives, often requesting donations. According to CDC, most of these fraudulent activities are being conducted by phone, utilizing software to "spoof" phone calls to make them appear as if they are coming from phone numbers that may look familiar. CDC advises consumers to avoid answering calls from numbers they do not recognize, and to avoid sharing personal information over the phone. In addition, CDC notes that no federal agency will request donations from the general public. Suspicious phone calls may be reported to the Federal Communications Commission.

More information on the scams is available on the CDC website at *https://www.cdc.gov/media/phishing.html.*

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COVID-19 testing services, IOEM recognizes pharmacies as health care facilities in which PPE can be provided. By completing the IOEM 123 survey, pharmacies involved in both POCT and collection site testing may receive PPE for a 10-day supply at a time, following the approval of the application for the grant. While the complexity of PPE differs from POCT to collection site testing, pharmacies can obtain these supplies using IOEM services. Further, the Board is supportive of Idaho State University (ISU) College of Pharmacy's efforts to create and disseminate educational pieces for employees of pharmacies for the donning and doffing of PPE and the testing options that are available, as well as completing the medical billing process successfully.

As grant details are being finalized, a clear pathway has been established within existing COVID-19 testing sites that can be integrated and developed for POCT and lab-based testing. The Board, pharmacists, and other governmental and local entities are collectively engaged in providing testing materials, PPE, and educational resources to pharmacies in order to implement testing in pharmacies across Idaho. Visit the Board's website or call 208/334-2356 for more information.

Board Posts FAQ Guide to Website

Since statute changes went into effect on July 1, 2020, the Board has received several calls relating to the mandatory Idaho Prescription Drug Monitoring Program (PDMP) checking requirement for prescribers. In response, the Board staff has created FAQs on the topic and posted the information on the Board's website. The following are a few of the more common questions asked.

Q. When will I be expected to start PDMP mandatory checking?

A. Mandatory checking of the PDMP will begin October 1, 2020.

Q. How does the Board know that a provider has checked the PDMP each time a prescription is written for controlled substances (CS)?

A. The PDMP logs the inquiries it receives. The software has a program that can review the inquiries in relation to the prescription's date written and date filled. There is a provider version of that tool which, will enable the prescriber to view their search compliance as well.

Q. Are there any exceptions for PDMP mandatory checking?

A. There are exceptions in Senate Bill 1348, including for patients receiving treatment in an inpatient setting, hospice care, skilled nursing facility, and if the prescription is for a three-day supply or less. Further mention of exceptions is included under Title 37, Chapter 27.

Q. What is the specific compliance expectation for providers?

A. The PDMP is queried. No requirement for documentation on the prescription.

Q. Will the Board have its own verification program or will prescribers have to keep records that can be audited?

A. The Board has a PDMP compliance tool (computer software program) that will be used to assist in determining compliance. Providers will be able to check their own compliance once the software has been established for this.

Q. How is PDMP mandatory checking going to be enforced?

A. The subcommittee was clear that enforcement was to be educational initially. After a suitable period of time, enforcement could be a collaborative effort by the Board of Pharmacy and the respective licensing boards.

Q. Is the Board able to see when a prescriber opens the MSL-integrated PMP Gateway report prior to prescribing?

A. Yes, the prescriber's Gateway and delegate searches are included in the report.

Q. Can a prescriber's delegate check the PDMP? If so, will this qualify for the provider's requirement to check?

A. Yes, if the delegate is linked to the provider who does the check, this will satisfy the requirement. This is under the assumption that the delegate will report the findings to the provider.

Q. If a medication like buprenorphine or methadone is dispensed (not prescribed) at centers for behavioral health and Raise the Bottom Addiction Treatment, do they show up on the PDMP?

A. No, if the medication is dispensed, it does not have to be reported to PDMP because of the federal confidentiality laws.

Q. Will providers or pharmacies receive alerts regarding potential red flags of individuals who receive prescriptions for CS from multiple providers or pharmacies? If so, how?

A. The Board is authorized to provide unsolicited information to practitioners and pharmacists by Idaho Code §37-2730A(2):

> The board may release unsolicited information to pharmacists and practitioners when the release of information may be of assistance in preventing or avoiding inappropriate use of controlled substances.

Each calendar month, Board staff identifies patients who have obtained CS from five or more practitioners. Each practitioner and pharmacy that has serviced these patients is notified using the AWAR$_X$E PDMP program. The Board makes no judgments regarding these patients or their care; the notice is sent only to ensure that each practitioner is aware of the CS obtained by the patient. It is up to the practitioner to decide if further action is appropriate. The number of patients has declined over the last five years. One reason is better analysis of the data as long-term care providers and cancer treatment providers are identified. The Board believes the other reason is due to the unsolicited reports program bringing awareness to providers.

Q. When utilizing electronic medical records (EMRs) and electronic health records, I am not getting credit for checking the PDMP, even if I have checked it. What is the solution to this issue?

A. This may occur when the EMR uses a provider's National Provider Identifier (NPI) for validation and the PDMP does not have the provider's NPI in its demographics. The Board has been able to resolve this issue very easily by adding

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the NPI. In addition, the Board has been working on updating all PDMP users' NPI numbers. If a provider does run into the issue of not being credited for PDMP checks, please contact Teresa Anderson at the Board office at teresa .anderson@bop.idaho.gov or 208/334-2356.

Welcome New Board Members

There have been a lot of changes on the Board in the last 18 months. Dr Chopski resigned from her position on the Board to take Dr Alex Adams' place as the executive director. Justin Messenger, PharmD, from Idaho Falls, ID, was appointed in August 2019, following a brief tenure held by Scott Killian, PharmD, from April to June 30, 2019. Dr Holly Henggeler has now fulfilled her commitment to the Board, and Kevin Ellis, PharmD, from McCall, ID, was appointed July 31, 2020.

Dr Messenger is a 2011 graduate of ISU College of Pharmacy. He is currently pursuing his master of business administration (MBA) at ISU. He intends to use his MBA education to continue improving processes, workflow, and inventory management. He spent several years as a retail pharmacist before pursuing a hospital career. He loves hospital pharmacy, though he misses the daily patient interaction.

Dr Messenger is active in the outdoors of Idaho with his wife and children. They enjoy rock climbing and snow skiing as often as possible.

Dr Ellis is a 1997 graduate of ISU College of Pharmacy. He worked with Rite Aid pharmacies for 20 years before joining the team at Albertsons. Dr Ellis also provides relief to the McCall anticoagulation clinic that was started with grant funding in 2014. He currently holds the distinguished title of longest tenured pharmacist at McCall Hospital. He and his wife, Mary, have been married since 1998. Their daughter is headed to nursing school, while their son finishes up high school. Dr Ellis loves all things outdoors, including hunting, fishing, and golfing.

Since its inception, the Board has had the pleasure of having talented and dedicated professionals serve on the Board. Each member has served this state with compassion, diligence, and an abundant desire to serve the citizens well.

To serve on the Board of Pharmacy, candidates must meet the following criteria:

Idaho Code §54-1708. Qualifications of board members.

(1) The public member of the board of pharmacy shall be a resident of the state of Idaho who has attained the age of majority and shall not be nor shall he ever have been a member of the profession of pharmacy, the spouse of a member of the profession of pharmacy, or a person who has or has had a material financial interest in providing pharmacy service or any other activity directly related to the practice of pharmacy.

(2) The pharmacist members of the board of pharmacy shall at the time of their appointment and at all times thereafter:

(a) Be residents of the state of Idaho;

(b) Be licensed and in good standing to engage in the practice of pharmacy in the state of Idaho;

(c) Be engaged in the practice of pharmacy in the state of Idaho;

(d) Have five (5) years of experience in the practice of pharmacy in the state of Idaho after licensure.

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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