September 2020

# Iowa Board of Pharmacy News

*Published to promote compliance of pharmacy and drug law*

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## *Compliance Officers Implement New Procedures to Resume Site Visits*

Because of safety concerns surrounding the coronavirus disease 2019 (COVID-19) pandemic, compliance officers have been on hiatus from physical site visits for the past few months. Following guidance from the Iowa Department of Public Health, the Iowa Board of Pharmacy compliance team has resumed field inspections and investigations. Several new policies and procedures have been developed to ensure the safety of both the officers and the site's staff. Officers will be contacting each location prior to visiting to inquire about the health of their staff and the site's safety precautions. On the day of each visit, officers are required to check their temperature and fill out a form to screen for COVID-19 symptoms. To assist in contact tracing, the officers will be reporting back the time frame of their visit and providing the names of anyone they had prolonged contact with. As the state is reopening, it is important to take these precautions to protect the public from the spread of COVID-19 and to ensure the safe practice of pharmacy in Iowa.

## *Licensing Reform and Physician-Signed Immunization Protocols*

The Iowa Legislature enacted House File (HF) 2627, which implements several changes in professional licensure requirements to reduce burdens on individuals seeking professional licensure in Iowa. The new law limits the utilization of criminal convictions as a basis for license denial, revocation, or suspension; waives initial licensure fees for individuals at or below 200% of the federal poverty level; and creates a new pathway for professionals moving into the state to more efficiently obtain Iowa licensure. The new provisions take effect on January 1, 2021.

### Criminal Convictions

The bill amends the Iowa Administrative Code (IAC) to limit the use of an applicant's prior criminal convictions in denying, revoking, or suspending a license to only those criminal convictions that "directly relate to" the profession. Licensing boards must develop and make available a list of criminal convictions that may disqualify an individual from seeking professional licensure. Licensing boards must also develop a process by which an individual may request a board review of the individual's prior criminal history to determine if the convictions would render the individual ineligible for professional licensure. The Iowa Board of Pharmacy may charge an individual up to $25 for such board review and eligibility determination. The list of potentially disqualifying criminal convictions and process for preemptive criminal history review by the Board must be in place by January 1, 2021.

### Waiver of Fees

HF 2627 also implemented a requirement that licensing boards waive the licensure fees for first-time applicants whose household income does not exceed 200% of the federal poverty income guidelines. The waiver of fees would apply to application fees and those associated with a background check, if required for the specific license or registration, but would not apply to any examination fees. The fee waiver will only apply to individual applicants and will not apply to any business applicants. The waiver will be available beginning January 1, 2021, and will only be offered to individuals who are applying for the first time for the license or registration in this state. An applicant who is eligible for the fee waiver will be required to provide proof of household income.

### Physician-Signed Immunization Protocols Extended

HF 2627 also included an amendment late in the session that extended the repeal of IAC 155A.44, which authorizes pharmacists to administer immunizations under a physician-signed protocol. The IAC section was set to be repealed on June 30, 2020, but will now extend through June 30, 2021, and allow pharmacists to continue immuniz-

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# National Pharmacy Compliance News

**September 2020**

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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ing under a current and active physician-signed protocol. Pharmacists also have the option of immunizing under the Board's statewide protocol, with the immunizing pharmacist as the ordering practitioner.

## Frequency of Reporting to the PMP

As reported in the July 2020 *Newsletter,* the Iowa Prescription Monitoring Program (PMP) administrators have initiated a field audit of prescriptions dispensed and submitted to the PMP. The audit has identified a number of pharmacies that are not compliant with the IAC and Board rules, which require transmission of dispensing data to the program within one business day of the dispensing of the controlled substance (CS). The IAC was amended during the 2018 legislative session to require more frequent submission of dispensed CS prescriptions. Pharmacies should ensure that CS prescriptions are being transmitted to the PMP in the time frame required.

## USP General Chapter <800> Compliance

Board compliance officers have resumed routine inspections following a several-month pause due to the COVID-19 pandemic. Inspections now include a review of compliance with United States Pharmacopeia (USP) General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings. Prior to the enforcement date of December 1, 2019, inspections may have included an educational assessment of a pharmacy's compliance with USP <800>; however, inspections now include a full compliance review of the standards identified in the chapter. Pharmacies are reminded that the Board requires compliance with USP <800> for all handling of hazardous drugs (HDs) in a pharmacy – not just as it relates to nonsterile or sterile compounding.

Each pharmacy that handles HDs identified on the National Institute for Occupational Safety and Health list must have a list of the HDs it handles, complete and compliant policies and procedures, training documentation, and assessments of risk (unless the pharmacy plans to implement all the containment standards identified in the chapter). These documents must be available for inspection and copying by the Board. Recent inspections have found that the pharmacist-in-charge (PIC) or pharmacy personnel are unaware of the location of these required documents. Many pharmacies have had these documents created on their behalf at the corporate level, but pharmacy personnel must still be knowledgeable of their contents and be able to locate the information for compliance officer review.

- Each pharmacy must have access to appropriate products to clean up an HD spill. If bodily fluid spill kits are utilized, the pharmacy must have documentation that the kit is sufficient to deactivate, decontaminate, and clean an HD spill in addition to the labeled usage.
- Each pharmacy must have appropriate products to deactivate and decontaminate equipment used in HD handling. Section 15 of USP Chapter <800> states: "All areas where HDs are handled and all reusable equipment and devices must be deactivated, decontaminated, and cleaned."
- Facilities should review the products listed within the chapter that accomplish each required step. For example, isopropyl alcohol is not listed as a deactivating agent, but is listed as a decontamination agent. Any information about specific products obtained in regard to product function per the manufacturer may be retained and referenced.
- USP Chapter <800> Section 15 (Deactivating, Decontaminating, Cleaning, and Disinfecting) does not list a required frequency for decontamination/deactivation procedures in regard to counting equipment.
- USP Chapter <800> Section 12 (Dispensing Final Dosage Forms) gives guidance for equipment used for counting/repackaging of HDs and states: "Clean equipment should be dedicated for use with HDs and should be decontaminated after every use."
- The pharmacy may determine the frequency with which counting equipment used for dispensing final dosage forms is deactivated/decontaminated/cleaned, but each facility must have products to perform those functions as required by Section 15.
- Pharmacies must consider each HD and dosage form individually to determine which product leaves residue that could affect personnel or contaminate subsequent prescriptions.

## Curbside Deliveries Surging With Pandemic

Curbside delivery has surged during COVID-19 and has given some patients a safer option to avoid unnecessary exposure. It can be very beneficial to people who are immunocompromised or have mobility issues, such as the elderly population. However, it also changes the prescription dispensing process and can place additional burdens on the pharmacy. If pharmacies plan to continue this service indefinitely, it may be considered a permanent change requiring a written update in policies and procedures. This may just entail adding curbside deliveries

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to already existing procedures for home deliveries and mailing prescriptions, since these methods would include similar additional steps in dispensing. These procedures must include the required steps for pharmacists to counsel patients before they actually receive any new medications. If curbside delivery is not going to be a permanent change, it is still recommended that all pharmacy employees understand the differences in procedure and can help transition patients once the service is discontinued. As a reminder, any changes in operations due to the pandemic that are intended to be ongoing will need to be documented in policies and procedures.

## *CS Inventory When There Is a Change in PIC*

When there is a temporary or permanent change in the PIC, a CS inventory must be completed at the close of business on the last day the PIC is terminating his or her legal responsibility to the pharmacy (657 IAC 10.19(4)). This inventory serves as the final inventory for the vacating PIC and the initial inventory for the new PIC. While not required, it would be prudent for the incoming PIC to participate in the terminating PIC inventory since this inventory will most likely serve as the starting inventory for the incoming PIC.



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