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Iowa Board of Pharmacy News

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PMP Communication Module

In August 2019, the communication module of the Iowa Prescription Monitoring Program (PMP) went live. This module's notable features include Care Notes and a clinician-to-clinician direct messaging client. Care Notes are included in the NarxCare report and allow clinicians to append notes to the PMP record of a patient. These notes only become visible on the PMP report if clinicians have the communications module enabled. To create a new Care Note for a patient:

- Generate a NarxCare report for the patient.
- Within the report, there is a new section for Care Notes. Click **"add note"** to open the Care Note creation screen.
- Within a Care Note, you can also attach relevant documents, such as a pain contract or pharmacy lock-in information. Clinicians will also be able to set an expiration date for their Care Notes. Some electronic health record (EHR) integrations with the PMP will have a "share note" field, which is used to indicate whether a note should be shared with any authorized PMP user or only internally within your organization. Clinicians and state PMP administrators also have the ability to edit their own Care Notes within the PMP. When viewing a patient's Care Notes, new notes will be displayed in bold until viewed. There is a mechanism in place for flagging a message/Care Note as inappropriate, to be submitted for review by a state PMP administrator.

The clinician-to-clinician direct messaging allows clinicians to communicate directly through the NarxCare component of the PMP. This feature also allows for information to be exchanged between clinicians regarding a single patient. Within the dashboard of the PMP there is now an inbox, which includes both the clinician's messages and the Care Notes that have been written. To send a message to another clinician through the PMP, first generate a NarxCare report for the patient, then, when viewing the Rx Graph section of the report, click on the prescriber(s) that you wish to message to begin the process. When a message is sent to another clinician regarding a patient, it automatically includes the NarxCare report for that patient.

More information regarding these new modules and instructions for use can be found at *https://pharmacy.iowa.gov/iowa-pmp-awarxe.*

Naloxone Administration Reporting Now Live in the Iowa PMP

Effective July 1, 2018, Iowa first responders (eg, emergency medical services, paramedics, firefighters, and police) were required to report the administration of a rescue opiate antagonist (eg, naloxone, Narcan®) to the state. These opioid antagonist administrations are now included in the Iowa PMP as part of the patient NarxCare report. The naloxone administration indicator (NAI), when present, will be displayed for providers and can be accessed via the Iowa PMP AWARxE portal, or through existing EHR integrations using PMP Gateway. If an NAI is present, authorized providers may click on the indicator to view additional details of the event(s), including the date and who administered the naloxone. The NAI is meant to provide additional insight into a patient's history as a tool to help you make informed clinical decisions for your patient.

Iowa PMP Field Audit Project

The Iowa PMP will soon begin an innovative project to audit prescriptions reported to the Iowa PMP. The audit will utilize a "field audit" approach and will include compliance officers collecting copies of controlled substance (CS) prescriptions as part of their routine inspections. The Iowa PMP hopes to formally initiate the project in July 2020. The audit results will be used to establish baseline reliability and validity of the Iowa PMP data as well as monitor and evaluate changes and trends over time.

National Pharmacy Compliance News

July 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.*

Naloxone Dispensing Program

The Iowa Board of Pharmacy, in collaboration with the Iowa Department of Public Health, plans to initiate and support a statewide naloxone distribution program. All community pharmacies across the state of Iowa will be permitted to participate and will be able to submit claims for naloxone (Narcan) nasal spray to a claims processor utilizing a BIN and PCN. Pharmacies will be reimbursed the cost of the Narcan nasal spray at the state Medicaid rate, plus a $20 dispensing fee. More information will be forthcoming as the project kicks off.

Governor Reynolds Signs Bills Into Law

On Monday, June 1, 2020, Governor Kim Reynolds signed Senate File (SF) 2119 and SF 2120 into law. SF 2119 makes updates to Iowa's Controlled Substances Act to codify substances that were temporarily scheduled by the Board through rulemaking. The bill also provides more general language regarding the scheduling or descheduling of Food and Drug Administration-approved cannabis-derived products.

SF 2120 provides clarity that veterinarians, although not required, may access the PMP. The bill also provides for the required reporting of Schedule V CS to the PMP.

The Board will be promulgating rules to implement the legislation.

Iowa PMP Update With CE On-Demand Webinar Now Live

Modernizing the PMP: Updates to the Iowa PMP – 2020

The course highlights recent enhancements made to Iowa's PMP. Specific topics include a brief introduction to the communications module and proactive or threshold reports, as well as a review of NarxCare – an advanced opioid use disorder management platform designed to provide prescribers and pharmacists with insights into patient prescription fill histories and behaviors. Additionally, a summary of House File 2377, commonly referred to as the "opioid bill," and its continued impact on clinical practice in the state of Iowa are discussed.

Visit the following links for the pharmacy and pharmacy technician courses.

- **Pharmacists** – *https://learn.ceimpact.com/library/course/2070.*
- **Pharmacy Technicians** – *https://learn.ceimpact.com/library/course/2104.*

Why Has the Option for 'Other' Been Removed on DEA Form 106?

If your pharmacy has had the unfortunate situation of discovering a loss or theft of CS recently, you may have noticed that the option to report the type of loss as "other" is no longer available on Drug Enforcement Administration (DEA) Form 106. The change to the form was made at DEA headquarters and was intended to ensure that pharmacies are accurately reporting a loss of CS. The purpose of DEA Form 106 is not, and was never, intended to serve as a reconciliation tool or to identify a record-keeping discrepancy. The reporting form is intended to report to DEA when CS have been diverted from the registrant's location.

DEA's stance is that a pharmacy should be able to identify and account for what happens to the CS under its control, so there should never be a time that a pharmacy simply cannot account for a discrepancy. If the pharmacy discovers a discrepancy in the inventory of a CS where diversion cannot be determined, the pharmacy should document the discrepancy and be prepared to provide an explanation to DEA but should not submit a DEA Form 106. DEA Form 106 is intended for known diversion by way of robbery, break-in, known employee pilferage, etc.

It is also important when completing DEA Form 106 in cases of known diversion to accurately identify the method of diversion.

- If the pharmacy is closed at the time of the diversion, the method of diversion would be a break-in.
- If the pharmacy is open at the time of the diversion, the method of diversion would be a robbery (not customer theft), regardless of the threat or use of a weapon.
- For cases of internal employee diversion, the method of diversion would be employee pilferage, but this should only be utilized if you can determine the identity of the individual responsible for the diversion or can be assured that the diversion was the result of employee pilferage. Do not simply select employee pilferage for lack of a better ("other") option.

Failure to Report – Theft or Loss of CS

Part of the responsibilities of being a licensee or registrant of the Board is notifying the Board when another licensee or registrant has violated laws, rules, or regulations. In particular, one situation where the Board finds this notice is lacking is when a licensee or registrant is responsible for the loss of CS. The Board routinely

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receives a DEA Form 106 that reports theft or loss of CS with the reason identified as "employee pilferage." In these situations, however, the Board is to be notified immediately of theft or loss when a licensee or registrant is responsible for the theft or loss (see Iowa Administrative Code (IAC) 657-10.21(1)). The pharmacy is responsible for providing this immediate notice to the Board, but a corresponding liability rests with the pharmacist-in-charge (PIC) or other pharmacy staff members who are obligated to notify the Board of such acts by another licensee or registrant (see IAC 657-36.6(17)).

Required Elements on Prescriptions Issued by Physician Assistants

During the 2020 session of the Iowa Legislature, SF 2357 was passed and signed by Governor Reynolds, which addresses the practice of physician assistants (PAs). Among the changes, the requirement that a prescription issued by a PA contain the name of the supervising physician has been removed. The bill was effective upon the governor's signature on March 18, 2020. Prescriptions issued by a PA are no longer required to include the name of the supervising physician.

Is It Legit? Verifying Licensure of Wholesale Distributors

While pharmacies have always been accustomed to periodic drug shortages, the current coronavirus disease 2019 pandemic has resulted in supply issues of numerous commonly dispensed prescription medications that may seem more critical than usual. When availability of important drugs is limited, there is a prime opportunity for new secondary wholesalers to enter the market. Although there are many reputable secondary wholesalers, others exist strictly to participate in the gray market. Emails and faxes from secondary wholesalers are making their way into pharmacies offering up products that are in short supply. But how can you be sure such offers are legitimate and that the wholesaler is authorized to distribute into the state of Iowa?

It is the responsibility of each pharmacy and its PIC to ensure that all prescription drugs and devices purchased come from an Iowa-licensed wholesale distributor.

Verification can be accomplished online or by contacting the wholesaler directly to request a copy of its Iowa wholesale distributor license certificate. Starting in January 2019, the Board began requiring all wholesale drug distributors to obtain Drug Distributor Accreditation (formerly known as Verified-Accredited Wholesale Distributors® accreditation) as a condition of licensure. While the Drug Distributor Accreditation approval process is rigorous, it is a key factor in preventing counterfeit drugs from finding their way into Iowa pharmacies.

Exert due diligence if you are considering obtaining prescription medications from a source other than your usual vendor. Any questions regarding wholesaler verification can be directed to the Board compliance officer assigned to your pharmacy.

The *Iowa Board of Pharmacy News* is published by the Iowa 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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