



# State of Ohio Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## Updates From OARRS

### Reminder – Diagnosis Code Requirement

Rule 4729-5-30 of the Ohio Administrative Code (OAC) requires prescribers, except for veterinarians, to indicate the first four alphanumeric characters of the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) medical diagnosis code (eg, M16.5) or the Code on Dental Procedures and Nomenclature (CDT code) on all prescriptions for controlled substances. This information should be reported to the Ohio Automated Rx Reporting System (OARRS) in field DSP25 of your American Society for Automation in Pharmacy (ASAP) version 4.2A upload.

**Important:** Paragraph (K) of rule 4729-5-30 permits the processing of a prescription without the diagnosis code. Per rule 4729-37-04, if the code is not provided the pharmacy must indicate “NC” when reporting the diagnosis or procedure code to OARRS.

### Reminder – ASAP 4.2A Format Required for Reporting to OARRS

The ASAP 4.2A format required for reporting to OARRS has been effective since December 29, 2017.

Rule 4729-37-05 of the OAC requires the reporting of data to OARRS via the ASAP 4.2A standard. The dispenser guide outlining the ASAP 4.2A elements needed for the inclusion of this data is now available and can be accessed at [www.pharmacy.ohio.gov/ASAPupdate](http://www.pharmacy.ohio.gov/ASAPupdate).

As of December 29, 2017, OARRS will only accept the ASAP 4.2A format.

### Request OARRS Patient Reports

OAC 4729-5-20 requires a patient report to be requested prior to dispensing an outpatient prescription for a reported drug under any of the following circumstances:

- (1) A patient adds a different or new reported drug to their therapy that was not previously included;
- (2) An OARRS report has not been reviewed for that patient during the preceding 12 months, as indicated in the patient profile;
- (3) A prescriber is located outside the usual pharmacy geographic area;

- (4) A patient is from outside the usual pharmacy geographic area;
- (5) A pharmacist has reason to believe the patient has received prescriptions for reported drugs from more than one prescriber in the preceding three months, unless the prescriptions are from prescribers who practice at the same physical location; or
- (6) A patient is exhibiting signs of potential abuse or diversion. This includes, but is not limited to, overutilization, early refills, appearing overly sedated or intoxicated upon presenting a prescription for a reported drug, or an unfamiliar patient requesting a reported drug by specific name, street name, color, or identifying marks.

Reviewing the OARRS report is one tool in making a professional judgment in your decision to dispense or not dispense. The State of Ohio Board of Pharmacy has published a pocket card of when to check OARRS for both prescribers and pharmacists, which can be found at [www.pharmacy.ohio.gov/pocketcard](http://www.pharmacy.ohio.gov/pocketcard).

### Reminder – Dispensing of Emergency Refill of Medication Without a Prescription

Effective March 23, 2016, House Bill (HB) 188, commonly referred to as Kevin’s Law, modified the authority of pharmacists to dispense an emergency refill of medication without a prescription (Ohio Revised Code 4729.281).

Under certain conditions, a pharmacist is now permitted to dispense up to a 30-day supply for a non-controlled dangerous drug, or if the standard unit of dispensing for the drug exceeds a 30-day supply, the amount of the drug dispensed or sold does not exceed the standard unit of dispensing.

The Board has published guidance on this topic, which can be found [here](#).

### Resolution: Technician Registration

The Board has received nearly 22,000 applications for pharmacy technician registration; almost 19,000 technician applications have been processed. During April 2018, the Board transitioned to a new statewide eLicense system.

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# National Pharmacy Compliance News

August 2018



**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.

## **DEA Launches New Tool to Help Distributors Make Informed Decisions About Customers**

In February 2018, Drug Enforcement Administration (DEA) launched a new tool to assist drug manufacturers and distributors with their regulatory obligations under the Controlled Substances Act. The agency added a new feature to its Automation of Reports and Consolidated Orders System (ARCOS) Online Reporting System, a comprehensive drug reporting system that monitors the flow of controlled substances (CS) from their point of manufacture through commercial distribution channels to the point of sale at the dispensing/retail level. This newly added function will allow the more than 1,500 DEA-registered manufacturers and distributors to view the number of registrants who have sold a particular CS to a prospective customer in the last six months.

DEA regulations require distributors to both “know their customer” and to develop a system to identify and report suspicious orders. Manufacturers and distributors have asked DEA for assistance in fulfilling these obligations and have requested ARCOS information to help them determine if new customers are purchasing excessive quantities of CS. This new tool will provide valuable information for distributors to consider as part of their assessment. More details are available in a news release at [www.dea.gov/divisions/hq/2018/hq021418.shtml](http://www.dea.gov/divisions/hq/2018/hq021418.shtml).

## **PTCB Launches Certified Compounded Sterile Preparation Technician Program**

In January 2018, the Pharmacy Technician Certification Board (PTCB) launched the PTCB Certified Compounded Sterile Preparation Technician (CSPT) Program. To be eligible to apply, a technician must:

- ◆ Be a PTCB certified pharmacy technician (CPhT) in good standing; and
- ◆ Have completed either a PTCB-recognized sterile compounding education/training program and one year of continuous full-time compounded sterile preparation work experience, or three years of continuous full-time compounded sterile preparation work experience.

To earn CSPT Certification, eligible CPhTs are required to pass the CSPT Exam and submit competency attestation documentation from a qualified supervisor. The two-hour, 75-question CSPT Exam covers hazardous and nonhazardous compounded sterile products in the four domains of:

- ◆ Medications and components (17%);
- ◆ Facilities and equipment (22%);
- ◆ Sterile compounding procedures (53%); and
- ◆ Handling, packaging, storage, and disposal (8%).

The purpose of the Attestation Form is to document the candidate’s completion of required training and certain skill and competency assessments in such areas as aseptic technique, equipment cleaning, and use of personal protective equipment. More details about the CSPT Program are available on PTCB’s website at [www.ptcb.org](http://www.ptcb.org).

## **DEA Enables Mid-level Practitioners to Prescribe and Dispense Buprenorphine**

In January 2018, DEA announced a deregulatory measure that will make it easier for residents of underserved areas to receive treatment for opioid addiction. Nurse practitioners and physician assistants can now become Drug Drug Addiction Treatment Act-Waived qualifying practitioners, which gives them authority to prescribe and dispense the opioid maintenance drug buprenorphine from their offices. This final rule took effect January 22, 2018. More details about DEA’s amendments are available in a Federal Register notice titled “Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder” (Document Number: 2018-01173).

## **New CDC Training Offers CPE on Antibiotic Stewardship**

The Centers for Disease Control and Prevention’s (CDC’s) Office of Antibiotic Stewardship is offering free continuing education opportunities for health care professionals. Focused on judicious antibiotic prescribing and antibiotic resistance, the online training is offered in four sections, each with multiple modules. Section 1 of the “CDC Training on Antibiotic Stewardship” is open now and can be accessed at [www.train.org/cdctrain/course/1075730/compilation](http://www.train.org/cdctrain/course/1075730/compilation). Additional sections will be released throughout 2018. More information and resources about CDC’s national effort to help fight antibiotic resistance and improve antibiotic prescribing and use are available on CDC’s website at [www.cdc.gov/antibiotic-use/index.html](http://www.cdc.gov/antibiotic-use/index.html). CDC is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). This program meets the criteria for 0.258 CEUs of CPE credit. The ACPE Universal Activity Number is 0387-0000-18-031-H05-P.

## **Walmart to Provide Free Solution to Dispose of Medications With Schedule II Prescriptions**

In partnership with Walmart, DisposeRx will provide a safe and easy way to neutralize unused, unwanted, or expired prescription opioids. DisposeRx developed a powdered product, also called DisposeRx, that permanently dissolves when mixed with water and sequesters excess opioids and other

drugs in a stiff, biodegradable gel that can be safely thrown in the trash. Walmart will provide a free packet of DisposeRx with every new Schedule II prescription filled at its 4,700 pharmacies nationwide. “This partnership with DisposeRx is an exciting opportunity for Walmart to protect the safety of its customers and public health. Unwanted or expired prescription medications left inside consumers’ medicine cabinets can be an easy source for those seeking to misuse or abuse a prescription drug,” said Pharmacy Clinical Services Manager for WalMart Health and Wellness and NABP Past President Jeanne D. Waggener, RPh, DPh. “We’re not just making it easy for patients to safely dispose of their medications, but we’re also helping prevent abuse before it starts.” Additional information is provided in a January 17, 2018 news release titled “Walmart Launches Groundbreaking Disposal Solution to Aid in Fight Against Opioid Abuse and Misuse.”

### **ASHP Research and Education Foundation Predicts Trends to Affect Pharmacy in 2018**

In the 2018 Pharmacy Forecast: Strategic Planning Advice for Pharmacy Departments in Hospitals and Health Systems, the American Society of Health-System Pharmacists (ASHP) Research and Education Foundation provides guidance on eight topics that will challenge pharmacy practice leaders in hospitals and health systems. Published in the January 15, 2018 issue of American Journal of Health-System Pharmacy, the new report focuses on the following areas:

- ◆ Therapeutic innovation;
- ◆ Data, analytics, and technology;
- ◆ Business of pharmacy;
- ◆ Pharmacy and health-system leadership;
- ◆ Advanced pharmacy technician roles;
- ◆ Population health management;
- ◆ Public health imperatives; and
- ◆ Coping with uncertainty and chaos.

The 2018 report is available at [www.ajhp.org/content/75/2/23](http://www.ajhp.org/content/75/2/23).

### **USP Encourages Pharmacists to Help Patients Find Quality Dietary Supplements**

Recall announcements, enforcement actions, and reports challenging the quality of dietary supplements are problematic issues facing pharmacists who want to ensure that the over-the-counter (OTC) products they are recommending to patients are of good quality. Many consumers purchase OTC dietary supplements and herbal products, often assuming they are regulated like prescription medications. While the law requires pharmaceuticals to meet specific quality standards set by the United States Pharmacopeial Convention (USP), the same requirements do not apply to supplements. For this reason, USP has created quality standards and a verification process specifically for these health products. Brands displaying the USP Verified Mark signal to the public that “what’s on their label is what’s in the bottle.” Health care

practitioners can learn more about USP’s efforts at [www.usp.org/dietary-supplements-herbal-medicines](http://www.usp.org/dietary-supplements-herbal-medicines).

Further, USP Dietary Supplement Verification Services are available to manufacturers and brands worldwide. They include Good Manufacturing Practice facility auditing, product quality control and manufacturing product documentation review, and product testing. Manufacturers that are participating in USP’s verification program for dietary supplements can be found at [www.usp.org/verification-services/program-participants](http://www.usp.org/verification-services/program-participants).

### **New CPE Monitor Subscription Plan Helps Pharmacists Track Compliance Via Mobile App**

To help pharmacists easily monitor their CPE compliance, NABP partnered with the Accreditation Council for Pharmacy Education (ACPE) to develop CPE Monitor Plus, a subscription service for CPE Monitor®. Launched in April 2018, the new subscription service enables pharmacists to perform a variety of advanced functions beyond the basic CPE Monitor service, including:

- ◆ viewing CPE credit status by state to verify at a glance how much CPE credit must be earned to satisfy license renewal requirements;
- ◆ uploading certificates from non-ACPE CPE courses and applying them to relevant state licenses;
- ◆ receiving email alerts when CPE cycle deadlines are approaching;
- ◆ viewing all transcripts and individual courses and generating simplified, automated reports;
- ◆ searching for additional ACPE activities via ACPE P.L.A.N. (Pharmacists’ Learning Assistance Network); and
- ◆ accessing ACPE CPD (Continuous Professional Development) via single sign on.

CPE Monitor Plus is available for an annual, renewable subscription fee of \$29.95, regardless of how many licenses a pharmacist has or adds at a later date. CPE Monitor Plus is only available via NABP’s new mobile app. Search for NABP e-Profile in Google Play Store (Android) or the App Store (iPhone).

The standard CPE Monitor service is still available for free and can also be accessed via the app or a desktop by signing in with NABP e-Profile login credentials.

For more information, visit [www.nabp.pharmacy/CPE](http://www.nabp.pharmacy/CPE).



*CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their CPE credit electronically*

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That transition has caused significant manual processing of the remaining applications. However, processing has also revealed a large number of applications still lacking required documentation to allow full processing. To provide clarity for employers and applicants, the Board adopts the following:

All pharmacy technicians who submitted application materials for registration by 11:59 PM on May 11, 2018, may continue to submit any outstanding documentation and this documentation must be received by the Board before 8 AM on August 17, 2018, or their license will be deemed abandoned in accordance with rule 4729:3-1-01 of the OAC.

Notwithstanding any prior resolution approved by the Board, an application deemed abandoned as of August 17, 2018, prohibits the applicant from continued practice as any classification of technician and precludes employment as any classification of technician.

Pharmacy technician applicants subject to this resolution may continue to practice until 11:59 PM on August 17, 2018, unless otherwise notified in a Notice of Opportunity for Hearing letter proposing to deny the applicant's registration. On August 18, 2018, all individuals working as a pharmacy technician or technician trainee must hold a valid registration issued by the Board.

This resolution replaces Resolution R-2018-297 that was approved on April 9, 2018, and was adopted on June 4, 2018.

### ***Delayed Implementation of the Pharmacist and Intern Duty to Report Rules***

Please be advised that the pharmacist and pharmacy intern duty to report rules that were originally scheduled to go into effect on May 1, 2018, have been delayed. The Board is delaying the implementation of the rule to gather additional feedback from the pharmacy community and to address outstanding concerns.

When the rules go into effect, notification will be provided via an E-News Update and will also be posted to the Board's rule changes website at [www.pharmacy.ohio.gov/LawsRules/RuleChanges.aspx](http://www.pharmacy.ohio.gov/LawsRules/RuleChanges.aspx).

As a reminder, you can sign up for automatic email updates by visiting [www.pharmacy.ohio.gov/update](http://www.pharmacy.ohio.gov/update).

### ***Take the Time to Educate Yourself and Your Staff on Naloxone Dispensing***

Naloxone is one of the most effective tools at reversing an opioid overdose. To expand access to this lifesaving drug, laws were enacted to allow pharmacists and pharmacy interns to dispense this medication without a prescription to an at-risk opioid user or someone who can intervene in the event of an overdose (friend, family member, or another bystander).

Unfortunately, the Board continues to receive reports of pharmacies that have either turned away customers, even though the pharmacy notified the Board that they offer this service, or told customers that a prescription is required to obtain the naloxone.

It is strongly recommended that a pharmacy that has submitted notification to the Board that they are dispensing naloxone pursuant to a physician protocol train all staff (including pharmacy technicians and other staff who regularly interact with the public) about the availability of naloxone without a prescription.

If you are unsure of whether your pharmacy offers naloxone without a prescription, a full list of participating pharmacies can be accessed at [www.pharmacy.ohio.gov/naloxonepharmacy](http://www.pharmacy.ohio.gov/naloxonepharmacy).

Additionally, pharmacy staff are reminded that patient training should go beyond the provision of written materials and should include a comprehensive review of all the requirements stipulated in the rule. Your responsibility for patient education is critical as it could help save a life. For more information on these requirements as well as training materials, please visit [www.pharmacy.ohio.gov/naloxone](http://www.pharmacy.ohio.gov/naloxone).

### ***Medical Marijuana Update***

In June 2018, the Board launched the opening of the Ohio Medical Marijuana Control Program toll-free helpline. The toll-free helpline responds to inquiries from patients, caregivers, and health professionals regarding adverse reactions to medical marijuana, and provides information about available services and additional assistance as needed. The contact line can be reached at 1-833/4OH-MMCP (1-833/464-6627).

The Board has continued to receive questions about cannabidiol (CBD) oil (derived from hemp or derived from marijuana). HB 523, which created the state's Medical Marijuana Control Program, made no exception for CBD oil. HB 523 includes CBD oil in the definition of marijuana, regardless of whether it is an extract or wholly synthesized.

All marijuana products will need to be dispensed in a licensed Medical Marijuana Control Program dispensary. Those marijuana products will have to comply with the rules and regulations of the program. All products must have a known source, as well as known quantities of active ingredients. Testing procedures will be conducted by testing laboratories licensed by the Ohio Department of Commerce.

As the Medical Marijuana Control Program becomes operational this fall, the Board will continue to provide updates through the program's website at [www.medicalmarijuana.ohio.gov](http://www.medicalmarijuana.ohio.gov).

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