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Iowa Board of Pharmacy News

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Online License and Registration Renewals

The Iowa Board of Pharmacy has converted its legacy licensing database to iGov Solutions, LLC's licensing and enforcement management system, also known as iLEMS. You may now log on to *https://iowa.igovsolution.com/iboponline/User_login.aspx* and create a user profile. Through this portal, individuals can manage personal information online, including updating address and employment information.

A cornerstone to this system is that it allows licensees and registrants to renew and pay for licenses and registrations online through their respective user profiles. Pharmacists, technicians, and individual Controlled Substance Act (CSA) registrants are able to renew through the online portal. Additional license and registration categories will be added and given online renewal permissions throughout 2018. Businesses, including pharmacies, will be able to renew licenses online starting November 1, 2018.

Please visit the Board's website at *https://pharmacy.iowa.gov/licensureregistration* for additional online services, including license verification and checking the status of pending applications.

PMP Data Integrity

It is vitally important that prescribers and pharmacists have access to complete, accurate, and current prescription monitoring program (PMP) data in order to continue to address the country's prescription drug abuse epidemic. Prescribers, excluding veterinarians, are now required to register with the Iowa PMP at the time they renew their individual controlled substance (CS) registration. Mandatory use of the PMP will be dictated by the prescribing professionals' respective licensing boards. Utilization of the PMP will undoubtedly increase exponentially.

The Board would like to stress that data submissions to the PMP must be accurate and timely. **Data submissions must occur no later than the next business day following the date of dispensing.** Pharmacists need to be mindful that on days their pharmacy is not open or does not dispense any CS prescriptions, a "zero report" must still be filed with the PMP.

Pharmacists need to exercise an abundance of caution when updating information within the pharmacy's prescription dispensing software. Recently, an incident occurred at a pharmacy where one prescriber's National Provider Identifier (NPI) number was added in error to another provider's file within the pharmacy's dispensing software. The software was programmed to update Drug Enforcement Administration (DEA) information based on the practitioner's NPI. Consequently, the incorrect DEA information was updated and all future prescriptions, including CS, processed under that provider contained inaccurate data. This inaccurate data was then submitted to the PMP.

Prescribers, pharmacists, medical examiners, law enforcement officials, and researchers rely on the PMP data around the clock. The accuracy and timeliness of the data submitted to the PMP by pharmacies and dispensers is of utmost importance.

PMP – Integrate Now!

The Board deployed Appriss Health's PMP solution, PMP AWAR$_X$E, on April 4, 2018. The upgraded software is capable of integrating electronic health records and pharmacy dispensing software. Integration provides pharmacists and their delegates with no-click access to Narx Scores and one-click access to full NarxCare reports within a matter of seconds. Interfaces are currently built for the following pharmacy dispensing software:

- Rx1/Synercom
- PDX-Classic and Enterprise
- PioneerRx
- Rx30
- QS/1
- Mobile Medsoft-Helix

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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.

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.*

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.*

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 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.* 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.* 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.*

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.*

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.*

New CPE Monitor Subscription Service Makes Licensure Compliance Easier

To help pharmacists easily monitor their CPE compliance, NABP partnered with the Accreditation Council for Pharmacy Education (ACPE) to expand CPE Monitor® by offering a new subscription service. Users can keep their free, Standard version of CPE Monitor or upgrade to the Plus subscription plan. Launched in April 2018, the new Plus plan enables pharmacists to perform a variety of advanced functions beyond the Standard plan, including:

- Verifying how much CPE credit must be earned to satisfy renewal requirements;
- Receiving alerts when a license is nearing the end of a CPE cycle;
- Uploading non-ACPE credits to a licensee's e-Profile;
- Viewing consolidated transcripts for each state license;
- Connecting to My CPD, which allows licensees to maintain their continuing professional development (CPD) in one place; and
- Connecting to the Pharmacists' Learning Assistance Network, where licensees can easily search for ACPE-approved courses.

The Plus subscription is available for an annual, renewable fee of $29.95, regardless of how many licenses a pharmacist has or adds at a later date. It 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 plan 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.*

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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A pharmacy utilizing versions of these software programs may access PMP information within workflow for as little as $120 per pharmacy per year. Any pharmacists interested in integrating their pharmacy with the state's PMP should contact Jennifer Tiffany at jennifer.tiffany@iowa.gov.

Cannabidiol Oil – Can My Pharmacy Sell It?

The short answer? No.

There has been a multitude of confusion over the legality of selling oils labeled as containing cannabidiol (CBD) in Iowa pharmacies.

Various out-of-state CBD oil producers are marketing their products directly to pharmacies claiming they are legal to sell in all 50 states. These manufacturers are citing the "United States Farm Bill of 2014" as a legal means by which they may ship CBD oil containing less than 0.3% tetrahydrocannabinol (THC) throughout the country. There is a false belief held by the producers/distributors of these products that industrial hemp can be grown/distributed without restrictions. The truth is, there are restrictions outlined in the Farm Bill, but those restrictions are overlooked by the producers.

The Iowa Department of Public Health (IDPH) released the "IDPH Position Statement on CBD Product Availability in Iowa" on August 17, 2018. Included in the statement are the four exceptions in Iowa in which natural or synthetic cannabinoid products can be legally used. The exceptions are:

1. The following appropriately prescribed, Food and Drug Administration (FDA)-approved drugs: Marinol®, Syndros®, Cesamet®
2. Epidiolex®, produced by GW Pharmaceuticals, which has been approved by FDA but is awaiting action by DEA
3. Sativex®, produced by GW Pharmaceuticals, as part of an FDA-approved clinical trial
4. Products produced and approved pursuant to Iowa Code Chapter 124E, the Medical Cannabidiol Act, that contain less than 3% THC and are in a form recommended by the Medical Cannabidiol Board, approved by the Iowa Board of Medicine, and adopted by the IDPH pursuant to administrative rule (see 641—154.14(124E) for the approved forms).

Products manufactured in the state under the provisions of Iowa Code Chapter 124E will be available at IDPH-licensed dispensaries only, starting in late 2018.

The Iowa CSA, also known as Iowa Code Chapter 124, mirrors the federal CSA and classifies marijuana as a Schedule I CS, and defines marijuana in the following way:

> "Marijuana" means all parts of the plants of the genus Cannabis (this includes hemp), whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture or preparation of the plant, its seeds or resin, including tetrahydrocannabinols. It does not include the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, any other compound, manufacture, salt derivative, mixture, or preparation of the mature stalks (except the resin extracted therefrom), fiber, oil or cake or the sterilized seed of the plant which is incapable of germination.

The following is an excerpt from a DEA write-up called "Clarification of the New Drug Code (7350) for Marijuana Extract," which lays out which parts of the cannabis plant cannabinoids are found in, and which parts of the cannabis plants are legally defined as marijuana:

> . . . scientific literature indicates, cannabinoids, such as tetrahydrocannabinols (THC), cannabinols, and CBD, are found in the parts of the cannabis plant that fall within the federal and state CSA definition of marijuana,[1] such as the flowering tops, resin, and leaves.[2] According to the scientific literature, cannabinoids are not found in the parts of the cannabis plant that are excluded from the CSA definition of marijuana, except for trace amounts (typically, only parts per million)[3] that may be found where small quantities of resin adhere to the surface of seeds and mature stalk.[4] Thus, based on the scientific literature, it is not practical to produce extracts that contain more than trace amounts of cannabinoids using only the parts of the cannabis plant that are excluded from the CSA definition of marijuana, such as oil from the seeds. The industrial processes used to clean cannabis seeds and produce seed oil would likely further diminish any trace amounts of cannabinoids that end up in the finished product. However, as indicated above, if a product, such as oil from cannabis seeds, consisted solely of parts of the cannabis plant excluded from the CSA definition of marijuana, such product would

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not be included in the new drug code (7350) or in the drug code for marijuana (7360), even if it contained trace amounts of cannabinoids.[5]

1. The CSA states: "The term 'marihuana' means all parts of the plant Cannabis sativa L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination." 21 U.S.C. § 802(16).
2. H. Mölleken and H. Hussman. Cannabinoid in seed extracts of *Cannabis sativa* cultivars. *J. Int. Hemp Assoc.* 4(2): 73-79 (1997).
3. *See id.; see also* S. Ross et al., GC-MS Analysis of the Total Δ9-THC Content of Both Drug- and Fiber-Type Cannabis Seeds, *J. Anal. Toxic.,* Vol. 24, 715-717 (2000).
4. H. Mölleken, *supra.*
5. Nor would such a product be included under drug code 7370 (tetrahydrocannabinols). See *Hemp Industries Association v. DEA,* 357 F.3d 1012 (9th Cir. 2004) *(Hemp II).* However, as the Ninth Circuit stated in *Hemp II,* "when Congress excluded from the definition of marijuana 'mature stalks of such plant, fiber . . . , [and] oil or cake made from the seeds,' it also made an exception to the exception, and included 'resin extracted from' the excepted parts of the plant in the definition of marijuana, despite the stalks and seed exception." *Id.* at 1018. Thus, if an extract of cannabinoids were produced using extracted resin from any part of the cannabis plant (including the parts excluded from the CSA definition of marijuana), such an extract would be included in the CSA definition of marijuana.

Based on the cited literature, products purporting to be CBD oil that are being offered for sale over-the-counter are either derived from portions of the plants in the genus *Cannabis* prohibited under the CSA (ie, the resin), or the products are most likely misbranded as defined by FDA.

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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