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News



Arizona State Board of Pharmacy

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Board Mission

The Arizona State Board of Pharmacy protects the health, safety, and welfare of the citizens of Arizona by regulating the practice of pharmacy and the distribution, sale, and storage of prescription medications and devices and nonprescription medications.

The Board accomplishes its mission by:

- ◆ Issuing licenses to pharmacists, pharmacy interns, and pharmacy technicians;
- ◆ Issuing permits to pharmacies, manufacturers, wholesalers, and distributors;
- ◆ Conducting compliance inspections of permitted facilities;
- ◆ Investigating complaints and adjudicating violations of applicable state and federal laws and rules; and
- ◆ Promulgating and reviewing state rules and regulations.

The Board Is Now on Facebook

Follow the Board on Facebook for the latest news and updates at <https://www.facebook.com/Arizona-State-Board-of-Pharmacy-396869467321193>.

Licensing Software Upgrade

On June 12, 2017, the Board implemented a new licensing software. With the upgrade to its software, the Board anticipates a learning curve will be involved, resulting in slight delays. As we turn the corner and the software becomes a part of the Board's everyday process, the end

goal is to improve efficiencies in processing as well as improve communications with Board licensees and permittees. This is a very exciting time as the Board gets up to speed with technology.

House/Senate Bills Signed by the Governor

House Bill (HB) 2031: Pharmacy; virtual manufacturers; virtual wholesalers. Adds virtual wholesaler and virtual manufacturer to Board definitions, thereby giving the Board jurisdiction.

HB 2032: Pharmacy board; notice requirements. Requires a licensee or permittee to create an online profile using the Board's licensing software and allows a licensee or permittee to update the online profile in order to satisfy notice requirements. Modifies the information required to be reported.

HB 2033: Controlled substances; definition. Classifies specified drugs under the definitions of dangerous drugs and narcotic drugs and under controlled substances (CS) in Schedule I.

HB 2307: Controlled substances prescription monitoring program. Modifies the process for a medical practitioner to gain access to the Board's Controlled Substances Prescription Monitoring Program (CSPMP) central database tracking system and requires a person who is authorized to access the CSPMP database to do so using only the person's assigned identifier. Allows data collected from the CSPMP database to be used for the purpose of performing drug utilization review for CS. Increases the amount of money that may be transferred annually from the Board Fund to the CSPMP Fund, from \$395,795 to \$500,000.

HB 2308: Pharmacy board; logistics providers; permits. Requires a third-party logistics provider (3PL) that engages in the logistics services of prescription or over-the-counter dangerous drugs or devices into, within, or from the state of Arizona to hold a 3PL permit. Outlines storage practices, security requirements, and policies and procedures to be followed by each 3PL. Requires a 3PL to have a designated representative at each facility who meets certain requirements, including obtaining a fingerprint clearance card.



National Pharmacy

The applicability of articles in the *National Pharmacy Compliance* column can be determined by examining the law of your state.

WHO Launches Global Patient Safety Challenge on Medication Safety

To reduce severe, avoidable medication-associated harm in all countries by 50% over the next five years, the World Health Organization (WHO) has launched a worldwide initiative, the Global Patient Safety Challenge on Medication Safety. Medication errors cause at least one death every day and injure approximately 1.3 million people every year in the United States. In addition, low- and middle-income countries are estimated to have similar rates of medication-related adverse events as high-income countries.

The Global Patient Safety Challenge on Medication Safety aims to make improvements in each stage of the medication use process including prescribing, dispensing, administering, monitoring, and use. WHO intends to provide guidance and develop strategies, in addition to plans and tools to ensure that the medication process has the safety of patients at its core in all health care facilities.

Previous WHO Global Safety Challenges have included the Clean Care is Safer Care challenge on hand hygiene in 2005 and the Safe Surgery Saves Lives challenge in 2008. Additional information is available in the WHO press release available at <http://who.int/mediacentre/news/releases/2017/medication-related-errors/en>.

Continuous Quality Improvement and Patient Safety Organizations



This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at www.ismp.org. Email: ismpinfo@ismp.org.

Data from the ISMP Medication Errors Reporting Program reveals that medication-related problems are repetitive in nature. An incident of misuse in one setting is likely to repeat itself in another. Most importantly, the system changes that are necessary to prevent errors are similar, and a growing body of literature is available to guide these efforts. Tragically, too many organizations and individual providers do not believe similar incidents could happen to them. They fail to use information about errors occurring elsewhere as a roadmap for improvement in their own organization or practice. It is not until a serious error hits home that aggressive prevention efforts are implemented. With so much evidence-based information about error prevention at hand, there is little excuse for reacting to errors after they happen instead of preventing them.

The development and implementation of continuous quality improvement (CQI) efforts should be the highest priority in all pharmacies. Such efforts must be aimed specifically at preventing

well-known and repetitive dispensing errors. Pharmacies should seek out medication safety information and use it proactively to prevent medication errors. At the same time, safety issues recognized internally and/or reported by patients should be documented and analyzed, with a process to determine the best strategies to prevent future problems and methods to ensure implementation. An annual survey to assess consumer perceptions of the quality of pharmaceutical products and professional services could supply additional information upon which to base improvement strategies. For more information on CQI programs, visit Section 7 of Model Rules for the Practice of Pharmacy in *The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*.

Informational tools like the *ISMP Medication Safety Alert!* publication, or ISMP's *Quarterly Action Agenda*, which is a readily available list of medication problems compiled from the nation's reporting programs, can be a backbone of any CQI effort. The very purpose of the ISMP Medication Errors Reporting Program – indeed the purpose of any type of safety reporting program and the expert recommendations that stem from it – is to guide the implementation of quality improvement initiatives by practitioners and organizations.

It is important that certain information from the CQI proceedings and records of review be protected from discovery. Patient safety organizations (PSO) are organizations that share the goal of improving the quality and safety of health care delivery. Patient Safety Work Product (PSWP) is the information protected by the privilege and confidentiality protections of the Patient Safety Act and Patient Safety Rule. PSOs serve as independent, external experts who can collect, analyze, and aggregate PSWP locally, regionally, and nationally to develop insights into the underlying causes of patient safety events, thus improving quality by identifying and reducing the risks and hazards associated with patient care. Communications with PSOs are protected to allay fears of increased risk of liability because of collection and analysis of patient safety events.

For more information on PSOs, visit <https://www.pso.ahrq.gov/faq>.

NCPDP Releases Guide to Ensure Patients Get Their Medications During a Disaster

The National Council for Prescription Drug Programs (NCPDP) released the *NCPDP Emergency Preparedness Information* guide to assist pharmacists and other health care providers during a declared emergency. Prepared by the NCPDP Emergency Preparedness Committee, the guide provides resource information for eligibility and claims processing affecting displaced individuals. The guide is available at www.ncpdp.org/NCPDP/media/pdfs/NCPDPEmergencyPreparednessInformation_v1_4.pdf. Additional information for pharmacists about emergency preparedness is available on the NCPDP website at www.ncpdp.org/Resources/Emergency-Preparedness.

FDA Warns of Illnesses and Deaths in Pets Exposed to Fluorouracil

Food and Drug Administration (FDA) is alerting pharmacists that patients' pets are at risk of illness and death when exposed to the topical cancer medication fluorouracil cream USP 5% (5-FU) that is intended for use in people. Fluorouracil may also be marketed under the brand names Carac®, Efudex®, and

Compliance News

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News to a particular state or jurisdiction can only be ascertained
such state or jurisdiction.

Fluoroplex®. Very small amounts could be dangerous to household pets; thus, patients should use care when applying and storing the medication. FDA has received reports of five dogs that became ill and died after accidentally ingesting the topical cream, notes a Center for Veterinary Medicine Update available at www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm537434.htm.

Although FDA has not received any reports involving cats to date, cats are also expected to be extremely sensitive to fluorouracil cream. For instance, if an owner applies fluorouracil cream to an afflicted area and touches his or her cat, the cat may accidentally ingest the medication when grooming itself and suffer adverse events.

FDA advises that pharmacists who fill these prescriptions should advise patients with pets to prevent exposing their pet to the medication. Adverse events may be reported to FDA using the Form FDA 1932a, which may be obtained at www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm.

FDA Revises Final Guidance Documents on Bulk Drug Substances Used in Compounding

In January 2017, FDA issued revised versions of two final guidance documents regarding the use of bulk drug substances in compounding.

- ◆ Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act
- ◆ Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act

FDA clarified that the policies described in the guidances do not apply to inactive ingredients. Inactive ingredients are not included in the definition of a “bulk drug substance” and can be used in compounding without appearing on the bulk drug substances lists developed under sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act, if all applicable conditions are met.

As indicated on its website at www.fda.gov/Drugs/DrugSafety/ucm502075.htm, FDA will also provide regular updates to the categories of bulk drug substances described in the guidances. FDA previously stated that it would not evaluate new nominations for placement in one of the three categories until after it completed its review of substances already nominated with adequate supporting information.

Now, the guidances state that FDA will determine after submissions are received whether new nominations, including renominations of substances with additional supporting information, have sufficient information for FDA to review them. After making that determination, FDA will place nominated substances in the appropriate category on FDA's website. FDA intends to update the categories with any new nominations the first business day of each month. This revised policy will further minimize unnecessary disruptions to patient treatment while FDA develops the lists of bulk drug substances for use in compounding.

The guidances are available online at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469120.pdf and www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469122.pdf.

APhA Resource Guide Applies JCPP Pharmacists' Patient Care Process to Immunization Services

The American Pharmacists Association (APhA) published a resource guide that applies the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists' Patient Care Process to pharmacy-based immunization services. The components of the Pharmacists' Patient Care Process to collect, assess, plan, implement, and follow-up should be implemented as routine practice along with the National Vaccine Advisory Committee Standards for Adult Immunization Practice, as noted in the resource guide, *Applying the Pharmacists' Patient Care Process to Immunization Services*. “[P]harmacists and other vaccine providers need to strive to constantly improve collaboration, communication, and documentation,” indicates the APhA guide. For more information, visit the APhA Immunization Center at www.pharmacist.com/immunization-center.

CPE Training on Older Adult Fall Prevention Available Online

Developed in collaboration with the Centers for Disease Control and Prevention (CDC) and the APhA, the Stopping Elderly Accidents, Deaths, and Injuries (STEADI) initiative is offering continuing pharmacy education (CPE) training for pharmacists to prevent falls in adults 65 and older. The training will provide strategies to help pharmacists screen older adults for fall risk, conduct medication review and management, and offer patient education. To participate in the free online training, “STEADI: The Pharmacist’s Role in Older Adult Fall Prevention,” visit the CDC website at www.cdc.gov/steadi/training.html for more information.

New FDA Drug Info Rounds Training Video Addresses the Combat Methamphetamine Epidemic Act

Drug Info Rounds, a series of online videos by FDA, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the latest Drug Info Rounds video, “Combat Methamphetamine Epidemic Act,” pharmacists discuss the legal requirements for the sale of over-the-counter drug products that contain pseudoephedrine. Drug Info Rounds was developed with contributions from pharmacists in FDA’s Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.

FDA Presents Series of CE Webinars for Students and Clinicians

FDA’s Division of Drug Information in the CDER presents a series of continuing education (CE) webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of FDA’s role in medication error prevention and prescription drug labeling. The webinars and presentation slides can be accessed on FDA’s website at www.fda.gov/DDIWebinars.

Senate Bill (SB) 1023: Dispensers; prescription drug monitoring. Addition of Schedule V CS dispensing to be reported to the CSPMP. Also, allows CSPMP data to be shared with the Arizona Department of Health Services (DHS) to implement a public health response to address opioid overdose or abuse.

SB 1029: Pharmacy board; licensure; fees. Modifies licensing time period for pharmacy technician trainees and removes proration fees for licenses and permits.

SB 1134: Pharmacy board; required permitting; violation. Requires a person in Arizona or in any other jurisdiction who sells drugs, devices, chemicals, or durable medical equipment within or into Arizona to hold a valid permit issued by the Board. Allows the Board to inspect or investigate any evidence that appears to show a person is or may be acting in violation and outlines actions that the Board may take in response.

Bills Not Sponsored by the Board

SB 1269: Pharmacists; scope of practice. Expands a pharmacist's scope of practice to include dispensing of emergency refills for certain medications, prescription and dispensing of tobacco cessation drug therapies, and prescription and administration of oral fluoride varnish, if outlined requirements are met.

SB 1377: Controlled substances; approved medications. Allows any compound, mixture, or preparation that contains cannabidiol to be prescribed in this state, if certain requirements are met.

HB 2382: Misbranding. Allows manufacturers to communicate studies for off-label use of medication with practitioners.

SB 1452: Health boards. Boards must post non-disciplinary action on the boards' websites. This does not apply to letters of concern or advisory letters. This bill implements term limits that allow a board member to serve two full terms.

HB 2493: Addresses drug overdose. Establishes the Drug Overdose Review Team in DHS. Also, modifies requirements relating to the dispensing and prescribing of an opioid antagonist for emergency purposes.

Disciplinary Actions and Updates – Other Health Boards

Arizona Board of Osteopathic Examiners in Medicine and Surgery

David Izenberg, DO #2253 – Interim consent agreement and order for practice restriction and evaluation. Practice restriction that prohibits him from prescribing or dispensing Schedule II, III, IV, and V medications and psychotropic medications. Respondent may not provide any recommendations for medical marijuana.

Julie Lynch, DO #006758 – Interim consent agreement findings of fact, conclusions of law, and stipulated order for suspension and evaluations. Respondent's license summarily suspended pending proceedings for revocation and other action by the Board. Effective February 28, 2017.

Jerry Olshan, DO #1376 – Interim order for practice restriction (suspension) and physical evaluation. Respondent's license to practice osteopathic medicine is

suspended, and respondent shall not practice medicine of any kind. Respondent is prohibited from prescribing any form of treatment or medications until receiving permission from the Board to do so. Effective March 17, 2017.

Christian Peters, DO #1203 – Consent agreement and order for non-disciplinary practice restriction. Respondent limited to practice only osteopathic manipulative medicine and will not apply for Drug Enforcement Administration registration without first receiving approval from the Board. Effective March 23, 2017.

Dale Ratcliffe, DO #4581 – Consent agreement and order. Respondent surrendered license and shall no longer engage in the practice of medicine.

Paul Ruble, DO #2504 – Consent agreement and order. Respondent surrendered license and shall no longer engage in the practice of medicine.

Benjamin Shnurman, DO #4389 – Consent agreement and order. Respondent surrendered license and shall no longer engage in the practice of medicine.

Arizona Medical Board

Richard Berger, MD #20624 – Order for surrender of license and consent to the same (non-disciplinary). Respondent ordered to surrender his license for the practice of allopathic medicine in the state of Arizona and return his certificate of licensure to the Board. Effective April 6, 2017.

Aldemir T. Coelho, MD #12445 – Order for letter of reprimand and probation. Respondent issued a letter of reprimand and was placed on probation for a period of six months with 20 hours of continuing medical education preapproved by the Board.

Kenneth B. Fleisch, MD #28922 – Order for surrender of license and consent to the same. Respondent ordered to surrender his license for the practice of allopathic medicine in the state of Arizona and return his certificate of licensure to the Board. Effective March 3, 2017.

Tristram G. Horton, MD #45637 – Order for surrender of license and consent to the same. Respondent ordered to surrender his license for the practice of allopathic medicine in the state of Arizona and return his certificate of licensure to the Board. Effective March 3, 2017.

Diana H. Hydzik, MD #29302 – Interim consent agreement practice limitation (non-disciplinary). Physician is prohibited from engaging in the practice of medicine until she applies to the Board and receives its affirmative permission to do so, as stated in paragraph five under the order. Effective May 5, 2017.

Satyendra K. Jain, MD #16809 – Interim consent agreement for practice limitation and assessment. Respondent prohibited from engaging in the practice of medicine.

David P. Knapp, MD #22830 – Interim consent agreement for practice restriction. Prohibited from engaging in the practice of medicine.

Christiana M. Lietzke, MD #48554 – Order for surrender of license and consent to the same. Respondent ordered to surrender her license for the practice of allopathic medicine in the state of Arizona and return her certificate of licensure to the Board. Effective March 3, 2017.

Continued from page 4

Jose Piscoya, MD #25569 – Interim consent agreement for practice restriction. Respondent is prohibited from engaging in the practice of medicine in the state of Arizona until he applies to the executive director and receives permission to do so. Effective March 2, 2017.

Gregory J. Porter, MD #14879 – Respondent's license to practice allopathic medicine in the state of Arizona is summarily restricted. Respondent is prohibited from prescribing CS in the state of Arizona, effective May 5, 2017. On May 8, 2018, notice of errata. Respondent to immediately cease prescribing of CS pending the outcome of a formal hearing.

Usman Chaudhary Ramzan, MD #41233 – Interim practice restriction. Respondent is prohibited from engaging in the practice of medicine until he applies to the executive director and receives permission to do so.

David A. Ruben, MD #11382 – Interim findings of fact, conclusions of law, and order for summary suspension of license. Respondent's license to practice medicine in the state of Arizona is summarily suspended. Respondent is prohibited from practicing medicine in the state of Arizona and is prohibited from prescribing any form of treatment. Effective April 6, 2017.

Domiciano E. Santos, MS #10120 – Respondent surrendered license, effective May 5, 2017.

Edward Chao Hung Teng, MD #47833 – Interim practice restriction. Respondent is prohibited from engaging in the practice of medicine.

Kapil H. Thakkar, MD # 51425 – Interim practice restriction. Respondent is prohibited from engaging in the practice of medicine until he applies to the executive director and receives permission to do so. Effective April 27, 2017.

Edward Young, MD #14737 – Respondent requested that license be inactivated with cause. Respondent may not practice medicine in the state of Arizona or any other state, territory, or district of the United States or a foreign country while license is inactive. He may not reactivate his license before completing a long-term residential care or inpatient hospital treatment program or both. The Board will then refer the matter for formal hearing. Effective March 27, 2017.

Arizona Regulatory Board of Physician Assistants

Nora D. Ellis, PA #3675 – Revocation, effective June 28, 2017.

Kimberly Hart, PA #5631 – Interim practice limitation (non-disciplinary). Respondent shall not practice medicine in the state of Arizona and is prohibited from prescribing any form of treatment, including prescription medications, until respondent applies to executive director and receives permission to do so. Effective April 10, 2017.

James G. Morphis, PA #3283 – Surrender, effective May 24, 2017.

Page 5 – July 2017

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