



Guam Board of Examiners for Pharmacy

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NABP 2017 Annual Meeting

Guam Board of Examiners for Pharmacy Member Maggie Greenwood attended the 113th Annual Meeting of the National Association of Boards of Pharmacy® (NABP®) in May in Orlando, FL. This meeting is one of many held by NABP for member boards to network, participate in education and business sessions, and vote on resolutions. The following are highlights of the four-day long meeting.

Naloxone and Beyond

State naloxone laws are evolving. Some states recognize pharmacists as holding prescriptive authority, while some states have protocols and laws in place for convenient access to the drug. Various ways pharmacists can help individuals suffering from opioid abuse were presented, including physician protocol for direct dispensing by pharmacists and interns. Additionally, discussion took place on naloxone being carried and administered by law enforcement.

Telehealth

Factors driving the push for telemedicine are lack of providers and consumer demand. Reimbursement for pharmacist services from Medicaid and Medicare was discussed, and speakers advised that it is essential to work with the appropriate state and local medical boards to start the process. The location of the patient determines which state licensing board governs physicians and pharmacists. Unlike Guam, most licensing jurisdictions have adopted more than just remote order entry into their telehealth practices.

Expanding Scopes of Practice

Advancing the pharmacy profession includes expanding roles beyond traditional dispensing. Laws and regulations to keep in line with this movement were discussed, including expanding the scope and duties of pharmacy technicians. Ideally, this would allow pharmacists to be involved in more clinical roles and

to participate in prescriptive authority and collaborative practice agreements. It is important to work together with your state's medical society and the legislature to demonstrate the benefits of pharmacists having prescription authority while preserving physicians' scope of practice. For example, Illinois, Idaho, Oregon, and many provinces of Canada have successfully implemented these changes in their statutes and rules and regulations.

Prescriptive authority for pharmacists is aided in large part by advancing the practice of pharmacy technicians. An example of this is the tech-check-tech practice, which is training and allowing pharmacy technicians to take verbal orders, transfer prescriptions, and administer immunizations.

Resolutions

Numerous resolutions were voted upon to amend NABP policies. One of the resolutions that passed addressed uniform unit-of-use packaging standards and resolved that NABP review existing unit-of-use packaging standards and revise the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*, if necessary, to assist in establishing consistency for packaging unit-of-use containers. Another resolution that passed addresses best practices for veterinary compounding. NABP will convene a task force of stakeholders to develop model regulations for the compounding of animal products.

Visit the Reports section under Publications and Reports on the NABP website at www.nabp.pharmacy for further details on the resolutions adopted at the 113th Annual Meeting.

A Review of the Professional Service Area

The professional service area is described in 25 Guam Administrative Rules (GAR) §13106 as a physical space within a pharmacy, of no less than 150 square feet, and includes a number of specified minimal requirements. The professional service area must have a dedicated area of 12 square feet for dispensing and compounding, and

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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.ncdp.org/NCPDP/media/pdf/NCPDPEmergencyPreparednessInformation_v1_4.pdf. Additional information for pharmacists about emergency preparedness is available on the NCPDP website at www.ncdp.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

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.

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must contain appropriate equipment and storage devices including, but not limited to, a refrigerator, balance, and sink with both hot and cold water. Section 13106 also mandates that in the absence of a licensed pharmacist, the professional service area must be secured and only the sale of nonprescription items is permitted. The rules require that there must be a physical barrier surrounding the professional service area that precludes access to the area by unlicensed personnel. This barrier must be locked in the absence of the pharmacist, and the managing pharmacist is responsible for compliance with all professional service area security requirements. Please be certain that your pharmacy is in compliance with this section.

Nonresident Pharmacy Application Is Now Available

The Board has a new application form (GBEP-22), Application for Pharmacy/Facility, to be used for both new and renewal licenses of a pharmacy, nonresident pharmacy, and wholesaler/distributor. The purpose of this new application is to streamline the initial and renewal application process, include nonresident pharmacies, and acquire more detailed information about the businesses and parties seeking licensure on Guam. Please contact the Health Professional Licensing Office (HPLO) for more information.

Change of Pharmacist-in-Charge

Effective January 14, 2017, the pharmacist-in-charge for Express Med 2 Pharmacy, Mangilao, GU, is Cheryl Marimla.

Telepharmacy Rules and Regulations

On May 21, 2017, the proposed rules and regulations promulgated by the Board governing telepharmacy practice across Guam/state lines became effective by operation of law. Please check the Guam Compiler of Law website at www.guamcourts.org/compileroflaws/gar.html for the updated Rules and Regulations, or contact the HPLO for more information.

License Renewal Season Is Approaching

Pharmacist and pharmacy technician licenses are up for renewal on September 30, 2017. The HPLO sent out a reminder email in June regarding new requirements for renewals. This includes a 2" x 2" passport-sized photo, which will be imbedded in the new license design. The new plastic card will be used as both a verification and identification license for added security. Additionally, the CPE Monitor® activity transcript furnished by NABP, the Accreditation Council for Pharmacy Education (ACPE), and ACPE providers may be used in place of GBEP-9 for reporting continuing pharmacy education (CPE) hours. Certificates and verification forms for each CPE program is not required unless requested by the Board. Please submit your application, fee, and documentation of CPE completion as referenced below.

25GAR Ch.13 §13104. Pharmacists Licensure Renewal. (a) Requirements. (1) Pharmacists licensed under P.L. 16-123 may be licensed biennially by applying for renewal between September 1st thru September 30th of each odd-numbered year and paying the fee specified by the Board. No pharmacist license renewal will be issued by the Board of Pharmacy unless the applicant, preceding the renewal application, has satisfactorily completed one and one-half (1.5) continuing pharmacy education program or programs approved by the Board within the preceding two-year period.

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