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Guam Board of Examiners for Pharmacy News

Published to promote compliance of pharmacy and drug law

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From the Chair

The Guam Board of Examiners for Pharmacy's purpose is to promote, preserve, and protect the health, safety, and welfare of the public. Pharmacy inspections are a part of the Board's mission in carrying out this purpose. In the past, the Board did not have dedicated staff to conduct routine inspections. The Board members usually conducted the inspections and included new applicants for pharmacies or wholesalers, as well as follow-up inspections whenever needed.

As of 2016, one of the Board's goals was to inspect all pharmacies, some of which had not been inspected in years. This goal was accomplished, although it took longer than expected. The Board has now instituted a policy of routine pharmacy and wholesaler inspections at a greater frequency.

The majority of boards of pharmacy across the country have dedicated individuals carrying out inspections in the form of inspectors or compliance officers. The Board therefore looked into having a dedicated pharmacy inspector who could examine more deeply the issues regarding official complaints reported to the Board. Fortunately, the Board has acquired two inspectors to act as agents of the Board, both experienced in pharmacy operation. They include a pharmacist and a pharmacy technician who have been conducting inspections recently throughout the community. Since the inception of these inspections, the inspectors have uncovered significant compliance issues with some pharmacies on Guam.

Currently, the Board's inspectors are working on a voluntary basis. The Board thanks them for their time and effort in supporting its purpose to regulate the profession in the interest of public protection.

Thomas J. Caruso, RPh
Chairman

Presentations by the Board at the Health Professional Regulatory Boards

In June and July 2018, the Guam Board of Examiners for Pharmacy appeared at the regular session meetings of the Guam Board of Medical Examiners, the Guam Board of Dental Examiners, and the Guam Board of Allied Health Examiners. The purpose of the Board of Pharmacy's appearances was to relay information about current issues regarding controlled substance (CS) prescriptions, with a focus on the mandatory compliance of valid CS prescriptions. Other issues discussed were safety with regard to opioid prescribing and insurance company limits on CS quantities. Prior authorization processes may take over seven days to resolve and result in the expiration of CS prescriptions. This delay may further affect patient care if prescription requirements are not met.

The recent Drug Enforcement Administration (DEA) inspections of pharmacies and the use of the Guam Prescription Drug Monitoring Program (PDMP) as a tool to prevent diversion were also mentioned. Though the Board's appearances have been well received by the other regulatory boards, **the emphasis by the Board of Pharmacy was to inform its registrants of the federal law requirements for prescribing CS and to ensure compliance to avoid diversion. Hefty fines may be imposed by DEA if violations are found.** The Board of Pharmacy appeared at the Guam Board of Nurse Examiners on August 2, 2018, to wrap up presentations.

DEA Inspections

DEA inspected various pharmacies throughout the island in May 2018. Complete results of DEA's visits are pending; however, it appears that some pharmacists are not exercising their corresponding responsibility when dispensing CS prescriptions. The duty lies with the pharmacist to determine whether the prescription meets federal and local law requirements. This excerpt regarding corresponding responsibility is from DEA's *Pharmacist's Manual:*

> A pharmacist also needs to know there is a corresponding responsibility for the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is an invalid prescription within the meaning

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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.*

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 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.*

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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> and intent of the CSA (21 U.S.C. § 829). The person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.
>
> A pharmacist is required to exercise sound professional judgment when making a determination about the legitimacy of a controlled substance prescription. Such a determination is made **before** the prescription is dispensed. The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious origin. To the contrary, the pharmacist who deliberately ignores a questionable prescription when there is reason to believe it was not issued for a legitimate medical purpose may be prosecuted along with the issuing practitioner, for knowingly and intentionally distributing controlled substances. Such action is a felony offense, which may result in the loss of one's business or professional license (see *United States v. Kershman,* 555 F.2d 198 [United States Court Of Appeals, Eighth Circuit, 1977]). (emphasis added)

If there is any doubt about a prescription's validity, the pharmacist should contact the prescriber and **document any authorizations or clarifications made with the prescriber.** For example, with regard to CS Schedule III-V prescriptions received via fax, a good practice would be to call the clinic where the fax originated from to verify with the prescriber, or his or her agent, if the original prescription was given to the patient or filed in the patient's chart. Another example is if a prescriber is known to be on vacation and/or his or her signature appears questionable. In this case, verify the information first, then follow protocols for reporting the incident to the proper authorities (DEA, the police, the Board, etc). One last example is if the patient's address is missing on a CS prescription. If this happens, notify the prescriber of the Code of Federal Regulations (CFR) requirements for valid CS prescriptions. Good patient care is at the forefront of pharmacy practice but preventing drug diversion, complying with federal and local laws, and adhering to best practices is a must. Fines by DEA may be a minimum of $10,000, so exercise your corresponding responsibility to avoid these penalties.

The Guam Pharmacists Association (GPhA) met in June 2018 to promote awareness to its members on how to prepare for a DEA audit. In addition, GPhA provided a handout of federal record-keeping requirements and discussed sections of the updated Guam CS Rules (effective January 21, 2018). More specifically, "Manufacture, Distribution, and Dispensing of Controlled Substances," Title 26, Division 1, Chapter 4, Article 16 was discussed. Pharmacists shared their inspection experiences in an effort to improve awareness and compliance and to be more prepared for future audits. Board inspectors have been auditing records to ensure compliance.

For an overview of federal and local CS requirements, please visit the following websites:

- Code of Federal Regulations: *www.deadiversion.usdoj.gov/21cfr/cfr/index.html*
- Title 21 United States Code Controlled Substances Act: *www.deadiversion.usdoj.gov/21cfr/21usc/index.html*
- Pharmacist's Manual: *www.deadiversion.usdoj.gov/pubs/manuals/pharm2/index.html*

As a reminder, follow local and federal record-keeping and logbook requirements when selling pseudoephedrine, ephedrine, or phenylpropanolamine products over-the-counter: *www.deadiversion.usdoj.gov/meth/q_a_cmea.htm.*

Continuing Education for Pharmacists

The renewal requirement for pharmacists is every two years by September 30 (in odd-numbered years) and must consist of 15 hours (1.5 continuing education units). In general, approved programs include Accreditation Council for Pharmacy Education (ACPE)-accredited continuing pharmacy education (CPE); however, other programs may be submitted to the Board for approval. Ten hours must consist of therapeutics and five hours may consist of administrative, socio-economic, and legal aspects of health care (25 Guam Administrative Rules Ch.13 §13105).

GPhA has sponsored or cosponsored continuing education programs that are ACPE-accredited: APhA's "Pharmacy-Based Immunization Delivery" certificate training program (20 contact hours); "Brief Tobacco Interventions: Skills Certification," which is a knowledge-based activity (5.5 contact hours); and the Centers for Disease Control and Prevention's presentation: "The Pharmacist's Role in Immunization: Schedules, Vaccine Management, and Common Concerns" (1.5 contact hours). All of these programs may be counted toward your renewal if completed between October 1, 2017, and September 30, 2019. Any ACPE-accredited programs completed online or live are automatically approved by the Board. Most applicants take advantage of CPE Monitor®, a service provided through the collaborative efforts of the National Association of Boards of Pharmacy® (NABP®), ACPE, and ACPE providers. The Board encourages the use of this service to assist in organizing and tracking CPE throughout licensing periods. Please continue to attach GBEP-9, Continuing Pharmacy Education Reporting Form, in addition to the transcript of CPE activity from NABP. This aids in a quicker and more efficient renewal process for all applicants during the renewal season.

Renewal Time for Facilities and Pharmacies

Renewal applications for facility (eg, wholesale distributor) and pharmacy permits (resident and nonresident) are due by **September 30, 2018.** You may visit the Health Professional Licensing Office at the Terlaje Building in Hagatna for an application or send a written request to the Board (mail, fax, or email) with your name, pharmacy or facility permit number, and mailing address, requesting that an application form be mailed to you. Submit the application form with the appropriate fee, using a check or money order, to the Treasurer of Guam.

Guam AWAR$_X$E

Mr Leo G. Casil, acting director for the Department of Public Health and Social Services, announced the launch of the new Guam PDMP software system in June 2018. The existing Guam PDMP account has automatically been transferred into the new system, Guam AWAR$_X$E, at *https://guam.pmpaware.net.*

Guam PDMP users should have received an email advising them on how to reset their password with the new system. The old website *(www.gupdmp.com)* is now obsolete. If you have any questions or concerns, please contact Guam AWAR$_X$E support directly at 833/276-0090. Technical assistance is available 24 hours a day, 365 days a year. For policy questions, you may contact Mr Jeffrey Pinaula, Guam PDMP administrator, at 671/735-7204 or jeffrey.pinaula@dphss.guam.gov.

New Board Member

The Board welcomes Gary Roy, RPh, as its newest member. Mr Roy will take the seat previously held by Margaret Greenwood, RPh. The Board would like to express much gratitude to Ms Greenwood; she has dedicated countless hours towards service to the Board and its mission to regulate the profession in the interest of public protection.

Required Notifications

As a reminder to all licensees, the Board requires notification of any change of ownership, management, location, or pharmacist-in-charge of a pharmacy, permanent closures of a pharmacy, any theft or loss of drugs or devices, and any conviction of any employee of any Guam, state, or federal drug laws. Please refer to 10 Guam Code Annotated Ch.12 §12630 for a complete list of notification requirements.

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