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123 Chalan Kareta • Mangilao, GU 96913-6304 • Tel: 671/735-7406 • Fax: 671/735-7413

Guam Board Adopts MPJE

The Guam Board of Examiners for Pharmacy is pleased to announce that the Multistate Pharmacy Jurisprudence Examination® (MPJE®) will now be required for pharmacist licensure. The exam combines federal- and jurisdiction-specific questions to test the pharmacy jurisprudence knowledge of prospective pharmacists. The Board's decision to adopt the MPJE into its licensure process was made to formalize and standardize the exam process for its candidates. In the past, the examination was written by the Board, offered on a candidate-to-candidate basis, and relied on a Board member's availability to proctor and score the exams. Candidates will now be able to sit for the exam in Guam or any of the available Pearson VUE professional centers nationwide. Since the Board's launch of the MPJE in January 2017, two candidates have taken the exam.

The process to operationalize the Guam MPJE took approximately one year. Thanks to the assistance of the National Association of Boards of Pharmacy® (NABP®) and the efforts by Board members, Guam is pleased to be the first United States territory (aside from the District of Columbia) to adopt the MPJE. This move ultimately allows the Board flexibility to focus on updating rules, addressing complaints, conducting routine inspections, and collaborating with the pharmacy community to promote safe pharmacy practice on our island.

As an ongoing commitment to retain NABP membership and collaboration with NABP member boards of pharmacy, the Board will be sending a representative to the upcoming MPJE Item Development Workshop in March 2017. This workshop will train members in the item development process of the MPJE.

Please visit the NABP website at *https://nabp.pharmacy/programs/mpje* for more information.

Letter to Providers and Clinic Managers

The following letter from the Board was recently sent to providers and clinic managers as a reminder of pharmacy technician limitations in reference to the supervisory requirement.

Hafa Adai Providers and Clinic Managers,

The Board would like to briefly review two important areas of the Pharmacy Practice Act: (1) limitations of pharmacy technician duties in accordance with supervision, and (2) requirements of a pharmacy label.

According to 10 GCA Chapter 12 (The Guam Pharmacy Practice Act), a Pharmacy Technician means personnel who assist in the practice of pharmacy under the personal and **direct** supervision of a pharmacist, and are registered with the Board.

The Board would like to emphasize **direct** supervision to include the physical presence of a licensed pharmacist on the premises whenever engaging in the practice of pharmacy. This includes IV admixture, compounding, interpreting, labeling and dispensing of prescription orders, provision of patient counseling, and any services necessary to provide pharmaceutical care in all areas of patient care.

This regulation is standard in most states and any deviation is regarded as a serious infraction [by] the licensees.

Additionally, the Board acknowledges that direct dispensing of medications by the provider allows immediate access to care for certain conditions. Licensed practitioners authorized under the laws of Guam to compound drugs and to dispense drugs to their patients in the practice of their respective professions shall meet the same standards, record keeping requirements and all other requirements for the dispensing of drugs applicable to pharmacists (10GCA Ch12 §12618).

The USP (United States Pharmacopeial Convention) issued the first universal "patient-centered" standards guiding content and appearance of prescription container labels, and should include the patient's name, medication name, strength, dose, route

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National Pharmacy

The applicability of articles in the *National Pharmacy Compliance*
by examining the law of

FDA Issues Final Rule Amending List of Drug Products That May Not Be Compounded

Food and Drug Administration (FDA) issued a final rule amending FDA's list of drug products that may not be compounded under certain sections of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that allow the marketing of unapproved compounded drugs. Drug products on the list may not be compounded because the drug products have been withdrawn or removed from the market for safety or effectiveness reasons, indicates FDA. The list may be found in the Code of Federal Regulations at Title 21, Section 216.24, at *www.ecfr.gov.*

The final rule adds 24 types of drugs to the withdrawn or removed list; modifies the withdrawn or removed list to allow one type of drug product to be compounded under certain circumstances; and clarifies that the withdrawn or removed list applies to sections 503A and 503B of the FD&C Act. The final rule is available at *www.gpo.gov/fdsys/pkg/FR-2016-10-07/pdf/2016-24333.pdf.* FDA provides more information online at *www.fda.gov/Drugs/DrugSafety/ucm524320.htm.*

Selected Medication Risks to Manage in 2017

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.*

Some medication safety risks are painfully apparent in an organization, while many others lie dormant in the system until an error or adverse event draws attention to them. ISMP thought it would be useful to describe selected medication safety risks for organizations to manage in 2017 that might otherwise fall off the radar screen.

Environmental Factors, Workflow, and Staffing Patterns – Poor Quality Lighting

Lighting is a crucial aspect of the physical environment that has been linked to medication safety.[1] Poor quality lighting has often impaired the highly visual tasks associated with medication use, thus leading to medication errors. Examples include tubing misconnections due to low lighting in a patient's room, infusion pumps that have been misprogrammed because of dim backlighting on the screens, and product selection errors in the pharmacy and patient care units caused by low lighting under a pharmacy hood or shadows around an automated dispensing cabinet (ADC).

Despite existing guidelines for lighting in health care, it has been a challenge to implement optimal lighting conditions for prescribing, dispensing, and administering medications. Recent literature reviews found that little system-wide action has been taken to increase staff awareness of the problem or improve the lighting.[1,2] This is largely because the tasks associated with medication use are varied and carried out under diverse physical conditions and in differing locations, and because there are differences in an individual's light requirements based on visual acuity and age. With an ever-increasing population of older health care providers, eye fatigue from computer work and task complexity, small font sizes on medication labels, poor background contrast, and glare or shadows have taken their toll on visual accuracy.[1,2]

Proper illumination improves both the accuracy and efficiency of medication-related tasks. Fluorescent cool white lamps or compact fluorescent lamps should be used in areas where critical tasks are performed, including on mobile medication carts, near ADCs, and in patients' rooms for nighttime administration of medications.[3,4] Administration of medications at night under low lighting to avoid disturbing the patient is an unsafe practice and should be avoided. Adjustable 50-watt high-intensity task lights are recommended when difficult-to-read prescriptions and product labels are encountered.[4] Illumination levels for computer order entry areas should be at least 75 foot-candles (fc), while 100-150 fc are needed when interpreting handwritten orders.[4] Medication preparation areas, medication verification areas, and patient counseling areas should have illumination levels between 90-150 fc.[4] Medication rooms should provide illumination at 100 fc.[4] Lighting levels should be increased if the workforce has an average age above 45 years. A magnifying glass and task light together can also significantly improve accuracy[3] and should be used on mobile medication carts (including those used with bar code medication verification systems)[4] and near ADCs.

References:

1. Chaudhury H, Mahmood A, Valente M. The effect of environmental design on reducing nursing errors and increasing efficiency in acute care settings: a review and analysis of the literature. *Environ Behav.* 2009;41(6):755-786.
2. Graves K. *Nurses' Decision Making Processes About Lighting During Medication Administration* [dissertation]. Denton: Texas Woman's University College of Nursing; 2014.
3. Grasha AF. Psychosocial factors, workload, and risk of medication errors. *US Pharm.* 2002;27(4):HS32-52.
4. United States Pharmacopeial Convention. Chapter <1066> Physical environments that promote safe medication use. *Revision Bulletin.* October 1, 2010;2-6. www.ismp.org/sc?id=1664.

DEA to Decrease Manufacturing Amount of Opioid Controlled Substances in 2017

Drug Enforcement Administration (DEA) is reducing the amount of almost every Schedule II opiate and opioid medication that may be manufactured in 2017 by 25% or more. Other medicines were reduced by more, such as hydrocodone, which will be 66% of last year's level, indicates the DEA news release. DEA notes that demand for these opioid medicines has declined based on sales data from IMS Health, a company that provides insurance companies with data on prescriptions written and prescription medications sold in the United States.

The aggregate production quota (APQ) established by the final order is the total amount of a controlled substance (CS) necessary to meet the estimated medical, scientific, research, industrial, and export needs for the year and for the maintenance

of reserve stocks. The 2017 APQ has been reduced for oxycodone, hydrocodone, fentanyl, hydromorphone, morphine, and other such medications. Much of this reduction is attributed to the elimination of a 25% buffer that was added to the APQ annually in 2013 through 2016 to guard against shortages. The purpose of quotas is to provide an adequate and uninterrupted supply for legitimate medical need of the types of Schedule I and II CS that have a potential for abuse, while limiting the amounts available to prevent diversion.

Additional details may be found in the DEA news release available at *www.dea.gov/divisions/hq/2016/hq100416.shtml* and in the final order available at *https://www.gpo.gov/fdsys/pkg/FR-2016-10-05/pdf/2016-23988.pdf*.

New CDC Brochure Offers Pharmacists Tips for Addressing Prescription Opioid Abuse and Overdose

Centers for Disease Control and Prevention (CDC) released a brochure encouraging pharmacists, who are an essential part of the health care team, to help prevent opioid abuse and overdose. The brochure, "Pharmacists: On the Front Lines," offers tips for communicating with patients who are receiving opioid therapy. In addition, the brochure offers tips on how to identify forged prescriptions and urges pharmacists to maintain collaborative working relationships with prescribers to improve patient outcomes. The brochure is available at *www.cdc.gov/drugoverdose/pdf/pharmacists_brochure-a.pdf*.

FDA Requires Boxed Warnings and Patient-Focused Medication Guides Indicating Serious Risks Related to Combined Use of Certain Opioid Medications and Benzodiazepines

FDA is requiring class-wide drug labeling changes to inform health care providers and patients of the serious risks associated with the combined use of certain opioid medications and benzodiazepines. Specifically, after an extensive review of the latest scientific evidence, FDA is requiring boxed warnings and patient-focused Medication Guides for prescription opioid analgesics, opioid-containing cough products, and benzodiazepines that provide information about the serious risks associated with using these medications at the same time. Risks include extreme sleepiness, respiratory depression, coma, and death.

FDA's news release indicates the changes are part of the agency's Opioids Action Plan, which focuses on policies aimed at reversing the prescription opioid abuse epidemic while providing patients in pain with access to effective and appropriate pain management. The public health crisis is evident through the significant rise of preventable overdose and death associated with the concurrent use of two drug classes, indicates FDA Commissioner Robert Califf, MD, in the press release, available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm*.

FDA's Division of Drug Information Offers CE Webinars for Students and Clinicians

FDA's Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information 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 drug shortages and prescription drug promotion. The webinars and presentation slides can be accessed on FDA's website at *www.fda.gov/DDIWebinars*.

FDA Approves Labeling Changes for All Prescription Testosterone Products

In October 2016, FDA approved class-wide labeling changes for all prescription testosterone products regarding the risks associated with abuse and dependence of the drug. The changes include adding a new warning as well as updating the Abuse and Dependence section to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other anabolic androgenic steroids (AAS). The Anabolic Steroids Control Act of 1990 placed AAS, including testosterone, in Schedule III of the Controlled Substances Act.

Prescription testosterone products are FDA-approved as hormone replacement therapy for men who have low testosterone due to certain medical conditions. However, testosterone and other AAS are abused by adults and adolescents, including athletes and body builders, notes FDA. FDA indicates the new warning will "alert prescribers to the abuse potential of testosterone and the serious adverse outcomes, especially those related to heart and mental health that have been reported in association with testosterone/AAS abuse." In addition, new labeling information in the Warning and Precautions section advises prescribers of the importance of measuring serum testosterone concentration if abuse is suspected.

FDA explains that abuse of testosterone, usually at doses higher than those typically prescribed and usually in conjunction with other AAS, is associated with serious safety risks affecting the heart, brain, liver, mental health, and endocrine system. Reported serious adverse outcomes include heart attack, heart failure, stroke, depression, hostility, aggression, liver toxicity, and male infertility. Individuals abusing high doses of testosterone have also reported withdrawal symptoms, such as depression, fatigue, irritability, loss of appetite, decreased libido, and insomnia. The FDA announcement is available at *www.fda.gov/Drugs/DrugSafety/ucm526206.htm*.

Latest FDA Drug Info Rounds Training Videos Available

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, "Extortion Scam," pharmacists discuss steps a potential victim could take if they receive a call from individuals posing as FDA and DEA agents. Drug Info Rounds is developed with contributions from pharmacists in FDA's 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*.

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of administration, frequency, purpose, special precautions (if any), expiration date, and [provider's] name. Please refer to . . . [United States Pharmacopeia 36 and the National Formulary 31 General Chapter <17>] for full description of current prescription labeling standards.

The Board regards patient safety as most important when carrying out its functions. Thank you for continuing to provide safe, patient-centered care to our community. Please feel free to contact the Guam Board of Examiners for Pharmacy for any questions or further information.

License Renewal Season Approaching!

Pharmacist and pharmacy technician licenses are up for renewal on September 30, 2017. The Board will now be accepting complete applications; however, renewal cards will not be issued until September. Pharmacist intern licenses are due July 1, 2017. Please submit your application, fee, and documentation of continuing education completion as referenced below.

25 GAR 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 [units (15 hours) in a] program or programs approved by the Board within the preceding two-year period.

NABP Interactive Forum Report

NABP holds many meetings, webinars, workshops, and forums for state board of pharmacy members across the country to communicate and discuss current issues. Among these meetings are the Interactive Forums. The goal of the Interactive Forums is to facilitate interaction among boards and provide closed sessions to discuss important and timely issues related to pharmacy regulation. This is a summary of the Interactive Member Forum held in December 2016, which was attended by Board Member Maggie Greenwood.

Inspections

Most states are conducting inspections every 18 months, with high-risk pharmacies (sterile compounding) inspected more frequently. Some states have full-time inspectors trained by national programs recognized by NABP. Some states also have compliance officers to advise pharmacists and others of methods of correction, provide highly technical information and education about laws and rules, and investigate complaints.

USP <797>

With United States Pharmacopeia (USP) Chapter <800> on the horizon, many states are still aiming for 100% compliance with Chapter <797>. Currently, 41 states require Chapters <795> and <797> compliance, while some adopt a "diet 797," with the strongest or high-risk items written into their laws.

Prescriptive Authority

Many states are expanding pharmacists' prescriptive authority for routine maintenance prescriptions to alleviate the pressure on providers. These include insulin syringes, test strips, and oral contraceptives. Canada is way ahead of the US in this endeavor, in that pharmacists can prescribe for minor ailments like gastroesophageal reflux disease, musculoskeletal strain, fungal infections, and bacterial skin infections. Some pharmacists in Canada may also schedule and administer different injections such as Twinrix® and Zostrix®. Recently in California, a qualified pharmacist may be licensed as an advanced practice pharmacist, and New Mexico recognizes pharmacist clinicians. These advanced practice pharmacists undergo specialized training recognized by their respective boards and hold collaborative practice agreements with providers.

Prescription Monitoring Programs

It is undeniable that all states desire prescription information to be connected and easily viewable in a timely manner, especially for bordering states. Financial assistance is offered by grants sponsored by the Centers for Disease Control and Prevention to maintain prescription monitoring programs (PMPs). Mandatory reporting is universal. Some states even require providers and pharmacists to report no activity, while some states require the providers to check the PMP **before** issuing a prescription for pain management. Additionally, some states send alert letters about patients who are drug-seeking and "doctor shopping." Ultimately, the goal is to have all pharmacies and providers register and use the PMP.

Naloxone

With the opioid epidemic nationwide, states are taking measures into their own hands to tackle the problem by making naloxone easier to access. Kentucky is very forward-thinking with this topic by allowing pharmacists to write for and dispense naloxone after being trained and certified by the Kentucky Board of Pharmacy. In Canada, naloxone is sold over-the-counter. This movement expands pharmacists' duties and responsibilities to educate on appropriate and proper use.

Ongoing Inspections Report

In the last quarter of 2016, the Guam Board initiated conducting routine inspections of pharmacies around the island. Institutional pharmacies and compounding pharmacies were first on the list. It is the goal of the Board to complete retail pharmacy inspections in the first quarter of 2017. If any managing pharmacists or pharmacists-in-charge have any questions about these routine inspections, feel free to contact Heather Narcis at the Health Professional Licensing Office (HPLO) at

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heather.narcis@dphss.guam.gov for a copy of the inspection checklist or for more information.

Significant Loss or Theft of Controlled Substance

In the unfortunate event of theft of controlled substances or significant loss, the following must be done to inform authorities both local and federal.

1. Notify Drug Enforcement Administration (DEA) directly within one business day of occurrence or discovery.
2. Notify the local police department and the Board.
3. Complete DEA Form 106.

Significant loss is not defined by DEA, but rather determined by the license holder. To aid in determining what constitutes a significant loss, consider your practice setting, patterns of losses (if any), and information or behavior suspect of diversion. Lastly, keep abreast of current news events involving diversion and communicate with colleagues when suspicious activity points to diversion potential.

Board Announcements

Regular session Board meetings are held on the third Thursday of the month at 7:30 AM at the HPLO. Watch for the public meeting announcement in the local newspaper as well as on the Guam Department of Public Health and Social Services website. The public is welcome to attend.

GPhA Family Day

The Guam Pharmacists Association (GPhA) is sponsoring a family day on Sunday, April 23, 2017. It will be held at the Pacific Star Hotel in the Chamorro Ballroom from noon to 4 PM, $10 per family.

The *Guam Board of Examiners for Pharmacy News* is published by the Guam Board of Examiners for 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.

Guam Board of Examiners for Pharmacy - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Amy Suhajda - Communications Manager