October 2016

Guam Board of Examiners for Pharmacy News

Published to promote compliance of pharmacy and drug law

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Hafa Adai, Registrants

The Guam Board of Examiners for Pharmacy has been tasked with many responsibilities over the past year. The Board is working to promote, preserve, and protect the public health, safety, and welfare by and through effective control and regulation of the practice of pharmacy. As stakeholders, you are welcome to attend Board meetings, which are typically held on the third Thursday of each month. Please contact the Health Professional Licensing Office (HPLO) for more information.

New Board Members and Staff

The Board has two new members appointed by the governor of Guam: Angelina Eustaquio, PharmD, and Racquel Sperrazzo, PharmD. The Board welcomes them. They are replacing Arthur Mariano, who served on the Board for over 13 years, and Julius Fernando. The Board's heartfelt thanks goes out to Arthur and Julius for all their hard work over the years. Also on the team is Heather Narcis at the HPLO, who is our secretary and a whole lot more. She is a godsend to the team. Rob Weinberg is the assistant attorney general, and he is helping the Board sort through the rules and regulations. Also helping out at the HPLO are Roma, Josephine, and Rosemarie. All of these wonderful ladies help us with messages, emails, and anything else the Board needs done.

NABP Current Events

Heather Narcis attended the National Association of Boards of Pharmacy® (NABP®) Program Review and Training in Mount Prospect, IL, in June 2016. In the past year, Board members and other staff members have attended other NABP-sponsored training sessions/meetings. These have been a great asset to the Board.

Board Events/Reminders

The Board will be giving the year's last jurisprudence examination on November 8, 2016. The exam will be given at the HPLO located in the Terlaje Building in Hagåtña, Guam, from 8 to 9 AM.

The Board held a public hearing in March 2016 regarding rules for telepharmacy and will be holding similar public hearings in the future to discuss other drafts of pharmacy rules and regulations/statutes. The drafts have been given to the stakeholders, the Guam Pharmacists Association, for their comments. Copies are available at the HPLO. The attorney general's office will review these drafts before they are forwarded to the Guam Legislature.

Multistate Pharmacy Jurisprudence Examination

The Board is planning to offer the Multistate Pharmacy Jurisprudence Examination® (MPJE®) for Guam in the future. The Board recently reviewed thousands of questions and is working with NABP to see this to fruition. This will allow pharmacist applicants to schedule the exam at their convenience from any approved testing center.

Board Inspections

You may have heard that the Board has been conducting routine inspections. The Board is currently conducting wholesaler and institutional inspections, and it will soon be conducting retail pharmacy inspections.

Please contact the Board office at 671/735-7408 for further information on any of the above topics.

NABP 112th Annual Meeting Highlights

Hafa Adai, Pharmacists and Technicians,

This past May, I was fortunate to represent Guam as the voting delegate for our island at the NABP 112th Annual Meeting in San Diego, CA. The four-day meeting was packed with information about many issues, with focus on telepharmacy, prescriptive authority, and the Drug Supply Chain Security Act (DSCSA).

Regarding telepharmacy, most states have gravitated toward broader lawmaking/rulemaking to be flexible, rather than on the stricter side. Some states use the terminology "remote medication processing" as still encompassing a form of telepharmacy, without having to make specific laws/rules separating the two ideas. Some states use the federal definition of a rural community in their law when applying telepharmacy, rather than defining in their state law where the practice is allowed, and some states restrict services

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National Vaccine Safety Surveillance Program Available for Reporting Adverse Events

The Vaccine Adverse Event Reporting System (VAERS) eSubmitter program, a national vaccine safety surveillance program cosponsored by the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA), is available for the reporting of any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States. VAERS information is analyzed by CDC and FDA to identify new safety concerns. VAERS reports can be filed by anyone, including health care providers, manufacturers, state immunization programs, and vaccine recipients. Vaccine recipients are encouraged to seek help from their health care provider when filling out the VAERS form. Health care providers can find information about submitting a report on the VAERS website at *https://vaers.hhs.gov/professionals/index*.

Improper and Unsafe Vaccine Storage

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.*

Few issues are more important than proper storage and handling of vaccines, because their ability to prevent disease is dependent on these factors. To maintain stability, most vaccines must be stored in a refrigerator or freezer, and many also require protection from light. Excessive heat or cold – even a single exposure in some instances – can reduce vaccine potency. These temperature excursions are often due to improper refrigeration or freezer units, inadequate thermostat controls, and refrigeration/freezer units with inadequate space to allow good air circulation and even temperatures.

Improper and unsafe storage can also result in serious errors caused by selecting the wrong vaccines, diluents, and other medications with look-alike names and/or labeling and packaging. Storing vaccines close to each other has led to dispensing and administering the wrong vaccine or wrong form of vaccine (eg, adult versus pediatric). Storing vaccines too close to non-biologic medications in a refrigerator or freezer has also led to serious adverse outcomes, particularly when the mix-up involved a vaccine and a high-alert medication. For example, vials of insulin have frequently been mistaken as influenza vaccine, and various neuromuscular blocking agents have been used to reconstitute vaccines or were mistaken as influenza or hepatitis B vaccines.

Store vaccines in their own dedicated refrigeration and freezer units. Regular temperature monitoring is necessary, and technology is available to assist with alarmed, continuous monitoring devices that can alert staff via email and pager if a unit is out of specified range. Separate vaccine vials and syringes into bins or other containers according to vaccine type and formulation, keeping diluents with the appropr iate vaccines. Never store different vaccines in the same containers. Do not store vaccines with similar labels, names, abbreviations, or overlapping components immediately next to each other or on the same shelf. Separate the storage areas of pediatric and adult formulations of vaccines. Label the specific locations where vaccines are stored to facilitate correct age-specific selection and to remind staff to combine the contents of vials. ISMP's March 26, 2015 newsletter[1] contains additional strategies, as does a Vaccine Storage & Handling Toolkit available from CDC.[2]

References

1. ISMP. Recommendations for practitioners to prevent vaccine errors. Part 2: analysis of ISMP vaccine errors reporting program (VERP). *ISMP Medication Safety Alert!* 2015;20(6):1-6.
2. CDC. Vaccine storage & handling toolkit. www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf. June 2016.

Coalition Reports Impact of Educational Efforts on Safe Acetaminophen Use

The Acetaminophen Awareness Coalition reports that progress has been made to increase consumer awareness about the safe use of acetaminophen. The coalition also notes a decline in unintentional overdoses. The National Poison Data System's 2015 report indicates unintentional acetaminophen exposures, including dosing errors and accidental misuse, have decreased through 2013 after a peak in 2009. In addition, a nationwide survey indicates the number of consumers who understand that exceeding the recommended daily dose of acetaminophen may lead to liver damage has increased to 87% in 2013 from 78% in 2010. The survey also reports the number of consumers who think it is important to check the medicine label for the maximum daily dose increased to 98% in 2013 from 93% in 2010.

Developed in 2011, the Know Your Dose campaign encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use. The Know Your Dose campaign offers a list of helpful health tips to share with patients, including the following:

(1) Read and follow the label.

(2) Know which medicines contain acetaminophen.

(3) Take only one medicine at a time that contains acetaminophen.
(4) Ask a health care provider or pharmacist about dosing instructions or medicines that contain acetaminophen.

Pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website, *www.knowyourdose.org*.

FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians

FDA's Division of Drug Information in the Center for Drug Evaluation and Research presents a series of 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 expanded access program and the pregnancy and lactation labeling rule. The webinars and presentation slides can be accessed on FDA's website at *www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm*.

Fresenius Kabi Recalls Sensorcaine-MPF (Bupivacaine HCl) Injection, USP

In April 2016, Fresenius Kabi USA recalled a single lot of Sensorcaine®-MPF (bupivacaine HCl) injection, USP, 0.75%, 7.5 mg/mL, 30 mL fill in a 30 mL vial, because of visible particulate matter characterized as glass observed by the company during inspection of reserve samples. The recalled product was shipped in the US to wholesaler and distributor outlets between March 4, 2016, and March 21, 2016, and has an expiration date of September 2019. The recall affects lot number 6111504, product code 470237, and National Drug Code number 63323-472-37. The product is supplied as 0.75% strength in a 30 mL single-dose flint molded vial and is packaged in units of 25. To date, Fresenius Kabi has not received any reports of adverse events regarding this recall, indicates the press release posted to the FDA website.

Health care facilities that have the affected lot are instructed to immediately discontinue distributing, dispensing, or using the lot and return all units to Fresenius Kabi. Distributors are instructed to immediately notify their customers who have been shipped or may have been shipped the recalled product. Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program at *www.fda.gov/MedWatch*. Additional details are available on FDA's website at *www.fda.gov/Safety/Recalls/ucm497812.htm*.

Oral Liquid Docusate Sodium by PharmaTech Recalled Due to Contamination

In July 2016, FDA alerted health care providers that PharmaTech, LLC, of Davie, FL, voluntarily recalled all non-expired lots of Diocto Liquid, a docusate sodium solution distributed by Rugby Laboratories of Livonia, MI. The affected product was distributed nationwide in one-pint (473 mL) bottles with a Rugby label. FDA confirmed the product has been contaminated with *Burkholderia cepacia,* a bacteria linked to an outbreak in five states. The safety alert indicates FDA has received several adverse event reports of *B. cepacia* infections in patients, and some of these reports identify liquid docusate sodium products manufactured by companies other than PharmaTech. FDA and CDC continue to investigate the extent of this issue in order to identify other potentially contaminated liquid docusate sodium products. FDA joins CDC in recommending that clinicians not use any liquid docusate sodium product as a stool softener or for any other medical purpose. Adverse events or side effects may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch*. More information may be found in the safety alert on FDA's website at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm511528.htm*.

NABP Seeks Pharmacists From Districts 1, 5, and 7 to Serve as Volunteer Item Writers

The National Association of Boards of Pharmacy® (NABP®) is seeking pharmacists who reside in states in the following districts to serve as volunteer item writers:

- **District 1:** Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.
- **District 5:** Iowa, Minnesota, Nebraska, North Dakota, and South Dakota.
- **District 7:** Alaska, Idaho, Montana, Oregon, Washington, and Wyoming.

In an effort to secure more individuals representative of these areas of the country, NABP encourages pharmacists in all areas of practice as well as school and college of pharmacy faculty who reside in these states to apply.

NABP uses volunteer item writers to develop questions for the following examination programs: North American Pharmacist Licensure Examination® (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), Pharmacy Curriculum Outcomes Assessment® (PCOA®), and Pharmacist Assessment for Remediation Evaluation® (PARE®).

Interested individuals should complete the online interest form available in the Meetings section of the NABP website. Individuals who are selected will receive further information on opportunities to attend and participate in NABP-hosted workshops.

For more information about NABP item writing, visit the Meetings section of the NABP website at *www.nabp.pharmacy*, or contact CompAssess@nabp.pharmacy.

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where there are pharmacies in the same community. When speaking with representatives from other states, it was comforting to know they also faced the same challenges and trepidation from retail entities in the beginning stages of their rule drafting. However, as telepharmacy evolved and was implemented, retail pharmacies became more active and looked for ways to expand their areas of patient services in the telepharmacy realm.

Another hot topic during the meeting was prescriptive authority. Several presentations were given describing the expansion of clinical services by pharmacists. In British Columbia, Canada, certified pharmacist prescribers are authorized to manage and prescribe Schedule II drugs, emergency contraception, injectables, and chronic disease medications. I was surprised to find out that 49 states have some form of prescriptive authority either by collaborative practice agreement or protocol for at least one category of medication.

The DSCSA was also talked about in depth, but many questions are left unanswered until Food and Drug Administration (FDA) comes up with specific rules. It is not known when those will be available. But in preparation, states have already started inserting into their rules separate definitions for third-party logistics providers (3PLs) and wholesalers to make it clear which license applies. If the home state does not license a 3PL, it may not be permitted to get a license in another state. States are also preparing by evaluating their rules to ensure no conflict or inconsistencies with requirements and standards of the DSCSA exist. However, as mentioned, many states are anxiously awaiting clear direction from FDA.

Resolutions voted on and passed were: 1. Study will be conducted to review and define the practices of "white bagging" and "brown bagging"; 2. Increasing access to naloxone rescue kits, including amending the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)* to include the prescribing and dispensing of kits; 3. Use of prescription monitoring program data to measure prescription drug abuse; 4. Study on regulations for pharmacy technicians to perform remote data entry; and 5. Initiate a task force on telepharmacy practice and allow development of practice models that are not unnecessarily restricted. Full resolution text may be viewed here.

Resolutions that did not pass were: 6. Communicating the importance of leadership skills and professionalism in pharmacy curriculum; and 7. Include a definition of pharmacist-patient relationship in the *Model Act.*

If anyone is interested in specific programming material presented during the meeting, please request through the Board office or send me an email.

Thank you,

Angelina Eustaquio, PharmD, BCPS
eustaquioam@gmail.com

Drug Diversion/Pseudoephedrine Abuse

Pharmacy is one of the most highly regulated professions. Pharmacists have many duties. One of the first must be the health and safety of our patients. Pharmacists also owe a duty to society in general. Pharmacists are the gatekeepers of dangerous drugs. In addition to controlling the use of opioids and other controlled substances, pharmacists must also contain the sales of pseudoephedrine products.

Prescription drug diversion is extremely common in the health care industry. Drug diversion is the redirection of a prescription drug from its lawful purpose to illicit use, whether or not there is criminal intent. Prescription drug abuse is at epidemic levels. Drug overdoses are the leading cause of accidental death in the nation, and roughly 100 people die from drug overdoses every day. The theft of prescription drugs is not limited to back-alley criminals, but can include employees, patients, and health care facility visitors. Internal diversion can also be called an "inside job," in which those committing the crime are employed by the pharmacy or even an outsider who is allowed access to the pharmacy department.

The most common scenario for internal diversion in the retail pharmacy setting is theft by those who have access to the pharmacy: interns, pharmacists, technicians, and even housekeeping. In most of these cases, it is not a drug trafficking issue, but the employee is addicted to prescription drugs and is trying to feed his or her habit. Keep in mind that detection is important not only to identify the problem, but to prevent it from developing. Direct observation of employee behaviors can be useful in identifying indicators of diversion. Things to watch for may include computer inventory that is off; prescriptions with fake patient names; changes in work habits, behavior, and appearance of employees; suspicious activity; and/or unexplained absences from work that occur on a regular basis.

Things to do to prevent internal diversion may include the following: conduct routine audits of drugs received versus receipts; have different individuals receive orders and put them away; keep unnecessary personnel from behind the counter; limit personnel who can order controlled substances; and have video surveillance.

Just remember these principles when filling prescriptions. Experience is on our side. If you think something is not right, it probably is not. Use common sense. If you trust the patient and the prescriber, it is probably a legitimate prescription. Ask questions. Talk to the patient or the prescriber. Yes, people lie. If a prescriber is writing opioid prescriptions for money, he or she will lie to you if you call him or her about its legitimacy. Do you remember how to validate a Drug Enforcement Administration (DEA) number? Add the first, third, and fifth digits together. Add the second, fourth, and sixth digits together, and then multiply the sum by two. Add these two results together. The last digit on the right must match the last digit of the DEA number. In Guam, check that the prescriber's Controlled Substances Registration is valid. Remember, pharmacists have a corresponding responsibility. So **validate** and breathe easy.

When reviewing the pseudoephedrine purchases allowed in Guam, whichever law is stricter is the one that must be followed, whether federal or local. Guam law states that two packages can be sold in a single transaction. Federal law is 3.6 grams per day or 9 grams per month. This amount includes all strengths and salts of pseudoephedrine and ephedrine.

New Registered Pharmacists, Interns, and Technicians

The following individuals have registered with the Board.

Pharmacists		
License Number	**Name**	**Date Issued**
PH0206	Spearman, Victor G.	July 23, 2015
PH0207	Nguyen, Khanh C.	July 23, 2015
PH0208	Nguyen, Liza D.	July 23, 2015
PH0209	Rentfro, Valerie C.	July 23, 2015
PH0210	Ezea, Christie C.	July 23, 2015
PH0211	Dargin, Andree M.	July 23, 2015
PH0212	Richwine, Catherine H.	July 23, 2015
PH0213	Garib-Sohan, Urvashi	July 23, 2015
PH0214	Snow, David L.	July 23, 2015
PH0215	Roy, Gary L.	July 23, 2015
PH0216	Oshiro, Darian M.	July 30, 2015
PH0217	Au Yeung, Chi Chiu	October 1, 2015
PH0218	Wilcox, Kyle J.	October 1, 2015
PH0219	Whitely, Conroy S.	October 1, 2015
PH0220	Louis, Linus	October 1, 2015
PH0221	Bryant, Cyrethea L.	October 1, 2015
PH0222	Nguyen, Tri Minh	October 1, 2015
PH0223	Florez, JoAnn D.	October 22, 2015
PH0224	Macera, Marc R.	October 22, 2015
PH0225	Starks, Patrick W.	October 22, 2015
PH0226	Lee, Una	December 3, 2015
PH0227	Gonzales, Alexis Rae G.	December 7, 2015
PH0228	Sylvester, Jeniffer	February 5, 2016
PH0229	Vo, Nam H.	April 7, 2016
PH0230	Cho, Moon Hee	April 7, 2016
PH0231	Park, Sung Wook	April 7, 2016
PH0232	Duarosan, Blanche Anne G.	May 11, 2016
PH0233	Lange, Burton W.	May 11, 2016

Pharmacy Interns		
License Number	**Name**	**Date Issued**
2015-001	Huang, Kuan-Lin	July 23, 2015
2015-002	Legislador, Joen Redd	December 10, 2015
2016-001	Manaloto, Claudine	July 16, 2016

Pharmacy Technicians		
License Number	**Name**	**Date Issued**
RT0055	Mores, Dilma Ancheta	October 22, 2015
RT0056	Rosalin, Franklin Q.	December 10, 2015
RT0057	Fresnoza, William	March 17, 2016
RT0058	Estella, Ashley Mae B.	July 16, 2016
RT0059	Garcia, Emelita A.	July 16, 2016
RCPT0114	Cho, Amy	July 23, 2015
RCPT0115	Emboltura, Earl Jon	July 23, 2015
RCPT0116	Singer, Darian E.	July 23, 2015
RCPT0117	Castro, Demetria M.	July 23, 2015
RCPT0118	Reyes, Katrina Rae	July 23, 2015
RCPT0119	Stokes, Makenzie	August 5, 2015
RCPT0120	Chambers, Del-Sherree	August 13, 2015
RCPT0121	Pablo, Saleena Ranae Perez	August 20, 2015
RCPT0122	Seo, Karen Park	August 20, 2015
RCPT0123	Dalmacio, Jason Melvin R.	October 1, 2015
RCPT0124	Bergan, Beth Ann	October 1, 2015
RCPT0125	McDonald, Josephine	October 1, 2015
RCPT0126	Fulgar, Robert N.	October 22, 2015
RCPT0127	Jetley, Patsylynn	October 22, 2015
RCPT0128	Montano, Dilma	October 22, 2015
RCPT0129	Brillantes, Ednie T.	November 19, 2015
RCPT0130	Borja, Preston D.	November 19, 2015
RCPT0131	Fortes, Marvin M.	February 5, 2016
RCPT0132	Marquez, Cristina	March 17, 2016
RCPT0133	Coronel, Gennyne G.	July 16, 2016
RCPT0134	Delos Reyes, Maria Emmanuelle S.	July 16, 2016
RCPT0135	Hemlani, Hanisha L.	July 16, 2016
RCPT0136	Shin, Jong Wook	July 16, 2016
RCPT0137	Kho, Giselle R.	July 28, 2016
RCPT0138	Villanueva, Judith S.	July 28, 2016
RCPT0139	Macatangay, Ginnie G.	July 28, 2016

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