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Guam Board of Examiners for Pharmacy News

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Message From the Chairman

Hafa Adai and welcome to another edition of the *Guam Board of Examiners for Pharmacy Newsletter!*

Since its establishment in 1982, the Guam Board of Examiners for Pharmacy has aimed to protect our island's health, safety, and welfare. This is achieved through the compliance of registrants with all applicable Guam and federal pharmacy rules and regulations.

Our membership with the National Association of Boards of Pharmacy® (NABP®) gives us additional support and services needed to update our island's health care community about relevant national pharmacy news, matters, and events. Continuous education and information dissemination are instrumental in achieving our Board's goals, and our active membership in NABP is key in making this happen.

I thank you for your support and wish you a pleasant reading!

Arthur S. Mariano, RPh
Chairman

New Registered Pharmacists

The Board wishes to congratulate the following pharmacists who have been recently registered to practice in the territory of Guam.

1) Thomas Rumph III
2) Jed Sana
3) Daisy Buduan
4) Manmeet Chadha
5) Michael Porter
6) Patrick Sosa
7) Janet Cruel
8) Philip Tagariello
9) Tami Morford
10) Thomas Rozewics
11) Anna Jane Bautista

Robberies in the Pharmacy

Pharmacies have always been an attractive target for robberies. To prevent a robbery is difficult, but not impossible. Those who rob pharmacies are often under the influence, desperate, impaired, paranoid, and highly unpredictable. Surviving a robbery unhurt and alive should be of paramount importance. No material goods in the pharmacy are worth the risk of harm to yourself, your staff, or your patients. It is very important that you are prepared in the event you may encounter this frightening experience.

Here are some tips to prevent robberies and what to do during a robbery:

- Install an alarm and obvious surveillance system. Cameras are to be in plain sight and should be focused on areas of concern, such as the pharmacy counter, storage areas, and customers entering and leaving the store.
- Conceal recorders and retain recordings as long as possible.
- Arrange stock shelves so that the most targeted drugs are not visible from the sales floor.
- Place more valuable items and controlled substances (CS) out of sight, behind the counter, and under lock and key.
- Train staff to be alert, observant, and watchful for suspicious behavior, such as when a customer spends an inordinate amount of time looking at the same relatively high-priced items, or loiters outside, by the cashier area, or by the pharmacy operations area. Is the customer seemingly resentful or uneasy when staff ask if they can assist? Is the customer constantly looking behind, left, or right as if to see if anyone is watching?
- Be aware of suspicious activity outside the store.
- Have good physical barriers to prevent the counter from being crossed easily.

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FDA's New Database Simplifies Searching for Guidance Documents

Food and Drug Administration (FDA) has released a new database that houses most FDA guidance documents for regulatory professionals. The guidance documents for nearly all FDA-regulated professions and industries are available in a searchable database that allows users to enter keywords that update automatically as they are typed. Search results may also be narrowed by product, date, document type, and other terms. The database also indicates whether there is an open comment period and the deadline for submitting comments.

The database can be accessed at *www.fda.gov/RegulatoryInformation/Guidances/default.htm*.

2014-2015 Targeted Medication Safety Best Practices for Hospitals

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.*

The purpose of the Targeted Medication Safety Best Practices (TMSBP) for Hospitals is to identify, inspire, and mobilize widespread, national adoption of consensus-based best practices on specific medication safety issues that continue to cause fatal and harmful errors in patients despite repeated warnings in ISMP publications. These best practices are realistic practices, already adopted by many organizations, upon which hospitals can focus their medication safety efforts. The best practices are applicable to all types of hospitals including, but not limited to, critical access hospitals, cancer hospitals, and children's hospitals. They may also be applicable to other health care settings, as well as non-inpatient areas of hospitals and hospital systems. These best practices have been reviewed by an external expert advisory panel and approved by the ISMP Board of Trustees. Related issues of the *ISMP Medication Safety Alert!* are referenced after each best practice.

Recurrent Issue of Serious Harm

Oral methotrexate for non-oncological indications administered daily instead of weekly or twice weekly is a recurrent issue and one of the six TMSBPs.

ISMP has published this error in seven *ISMP Medication Safety Alert!* issues from 1996 to 2013. Although dosed daily for oncology purposes, it is used weekly or twice weekly to treat a variety of autoimmune diseases (eg, psoriasis, severe rheumatoid arthritis). Error reports point to inadvertent ordering and/or entering as daily instead of weekly or twice weekly, and lack of patient education/understanding of medication dosing schedule. To minimize the risk of error, **Best Practice 2** calls for hospitals to:

a) Use a weekly dosage regimen default for oral methotrexate. If overridden to daily, require a hard stop verification of an appropriate oncologic indication.
b) Provide patient education by a pharmacist for all weekly oral methotrexate discharge orders.

Question: Does the best practice of a weekly frequency default for oral methotrexate apply to a specialty cancer hospital?

Answer: The intent of this best practice is to reduce errors when methotrexate is prescribed as a weekly regimen for non-oncologic or oncologic indications. Even when used for oncologic purposes, oral methotrexate is sometimes prescribed as a weekly regimen, not daily. Thus, this best practice applies to all patient care settings, including specialty cancer hospitals.

Teaching Points (Both Verbal and Written)

- Explain the weekly dosing schedule.
- Explain that taking extra doses is dangerous.
- Have the patient repeat back the instructions.
- Provide the patient with the free ISMP high-alert medication consumer leaflet on methotrexate (found at *www.ismp.org/AHRQ/default.asp)*.

To read all of the best practices, visit *www.ismp.org/Tools/BestPractices/default.asp.*

ACPE Releases Updated Definition of CPE and Guidance on CPD

The Accreditation Council for Pharmacy Education (ACPE) has released two documents that provide guidance and support for continuing pharmacy education (CPE) and continuing professional development (CPD). The two documents, approved by the ACPE board of directors, are described below.

- The revised *Definition of Continuing Education for the Profession of Pharmacy* defines the quality of CPE required by ACPE and the competencies required for CPE activity content. The *Definition* document will assist providers of CPE in planning activities that will be applicable to the professional development of pharmacists and certified pharmacy technicians.
- The *Guidance on Continuing Professional Development (CPD) for the Profession of Pharmacy* incorporates feedback from a broad survey of the pharmacy profession that was conducted in July 2014. The *Guidance* document provides details on the learning activities that may contribute to the professional development of both pharmacists and pharmacy technicians beyond CPE, and also "provides a process for pharmacists and pharmacy technicians to meet and maintain defined competencies in areas relevant to their respective professional responsibilities."

Additional information, including links to the documents, is available in a press release on the ACPE website at *www.acpe-accredit.org/pdf/ACPEAdvancesCPE-CPDforPharmacists.pdf*.

Hospira Issues Recall for Multiple Lots of Ketorolac Tromethamine Injection Due to Potential Contamination

Hospira, Inc, of Lake Forest, IL, has issued a voluntary recall of ketorolac tromethamine injection, USP in the United States and Singapore due to potential particulate matter. The presence of particulate was confirmed through a customer report of visible floating particulate that was identified as calcium-ketorolac crystals. If in-

jected, medications contaminated with particulate matter may cause localized inflammation, allergic reaction, granuloma formation, or microembolic effects. Multiple lots are impacted by this recall and are listed in a press release posted to the FDA website at *www.fda.gov/Safety/Recalls/ucm433857.htm*. The lots were distributed from February 2013 to December 2014 in the US. To date, there have been no cases of adverse events associated with this medication. Adverse reactions may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

FDA Warns of Counterfeit Cialis Tablets Entering the US

Potentially dangerous, counterfeit versions of Cialis® 20 mg tablets were intercepted in the mail before reaching a US consumer, warns FDA. Laboratory analysis of the counterfeit product showed that it contained multiple active ingredients that could lead to adverse effects or harm if used, indicates an FDA Drug Safety Announcement. The agency reminds US consumers to only buy prescription medications from state-licensed pharmacies located in the US. FDA notes that it cannot confirm that the manufacturing, quality, storage, and handling of products ordered from unlicensed websites follow US standards because the products are from an unknown source.

To help consumers identify these counterfeit medications, FDA provides guidelines in the safety announcement. For example, these counterfeits list "AUSTR81137" on the front of the bottle and lack a National Drug Code number. Other possible identifiers include misspellings and unusual colors on the label, and a manufacturer listed as "112 Wharf Road, WEST RYDE, NSW 2114" on the side of the bottle.

To date, FDA is not aware of any adverse events associated with these counterfeit medications; however, consumers are encouraged to talk to a health care provider about their condition and options for treatment if a counterfeit product was received.

The National Association of Boards of Pharmacy® (NABP®) has reviewed more than 10,900 websites selling prescription drugs to patients in the US and found that nearly 97% are operating out of compliance with pharmacy laws and practice standards established to protect the public health. To help consumers in the US find the safest sources for purchasing medications online, NABP developed the Verified Internet Pharmacy Practice Sites® (VIPPS®) program. NABP encourages consumers to look for the VIPPS Seal and to check NABP's list of accredited sites on the AWAR$_X$E® Prescription Drug Safety Program website. In addition, consumers may soon watch for pharmacy sites using the newly launched .pharmacy Top-Level Domain; sites in the domain (with a website address ending in .pharmacy) will be reviewed by NABP and approved only if they are legitimate online pharmacies or pharmacy resources adhering to applicable pharmacy laws and best practices.

Additional details on the counterfeit Cialis are available in a Drug Safety Announcement posted to the FDA website at *www.fda.gov/Drugs/DrugSafety/ucm431071.htm*. More information on VIPPS and other NABP programs is available in the Programs section of the NABP website, *www.nabp.net*.

New FDA Drug Info Rounds Training Videos Review Drug Disposal and REMS

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. The latest Drug Info Rounds videos are as follows.

- In "Disposal of Unused Medicines," pharmacists discuss how consumers can safely dispose of expired or unused medications to prevent abuse or misuse and accidental poisoning.
- In "REMS," pharmacists discuss the many components of Risk Evaluation and Mitigation Strategies (REMS) and how they can help manage a drug product with known or potential serious risks.

Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. These videos and previous Drug Info Rounds resources are available on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm*.

FDA Issues New Drug Labeling Rules to Benefit Pregnant, Breastfeeding Women

FDA announced new prescription drug labeling requirements that will clarify how medications might affect women who are pregnant or breastfeeding and men and women of reproductive potential. The final "Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling Rule" removes the previously used pregnancy letter categories – A, B, C, D, and X – and places information into three main categories:

- **Pregnancy:** Labor and delivery guidelines now fall under this category, which also now includes information for pregnancy exposure registries. Such registries track data on the effects of certain approved medications on pregnant and breastfeeding women.
- **Lactation:** Previously labeled "Nursing Mothers," this category provides information such as how much drug is secreted through breast milk and the potential effects on a breastfed infant.
- **Females and Males of Reproductive Potential:** This is a new category that includes information on how a certain medication might affect pregnancy testing, contraception, and infertility.

The new labeling changes go into effect on June 30, 2015. Over-the-counter medication labels will not be affected. The new rules are available for download through the *Federal Register* at *https://s3.amazonaws.com/public-inspection.federalregister.gov/2014-28241.pdf*.

FDA Approves Zohydro ER With Abuse-Deterrent Properties

In February 2015, FDA approved a new formulation of Zohydro® ER with abuse-deterrent properties. The new formulation uses a technology that allows the drug to maintain its release properties when used as intended, according to a press release from Zogenix. The abuse-deterrent system, known as BeadTek, incorporates "pharmaceutical excipients" that create a viscous gel when the medication is crushed and dissolved in a liquid or solvent, thus making the product more difficult to abuse through methods that involve crushing, breaking, or dissolving the drug. In early 2014, Zohydro ER became the first extended-release, single-ingredient hydrocodone product to receive approval for use in the US. Approval of the drug came under criticism, with some organizations arguing that the potential for addiction, abuse, and misuse could outweigh therapeutic benefits, in part because the drug lacked abuse-deterrent properties. Zogenix indicates that transition to the new abuse-deterrent formulation will take place in second quarter 2015.

Additional information on the new formulation is provided in a press release available on the Zogenix website at *http://ir.zogenix.com/phoenix.zhtml?c=220862&p=irol-newsArticle&cat=news&id=2012326*.

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- ♦ Management should conduct a thorough background screening and check on any applicant for a pharmacy operations job.
- ♦ Employers should check the status of their technician registrations to ensure that they are in compliance.
- ♦ Restrict the use of window signs or displays that block visibility from outside the store.
- ♦ During the robbery, stay calm and do exactly as you are told. No more, no less.
- ♦ Alerting the robber of any event or action you know is going to happen may upset the robber (eg, someone is due to arrive soon). When it is necessary to move to comply with the demands, inform the robber of what you are going to do and why.
- ♦ Listen carefully and do not resist. Take a step back and place your hands in front of you with palms held outward. Turn your body sideways to reduce target area.
- ♦ Activate panic button alarm only when you can do it secretly or when it is safe to do so. Take no chances!
- ♦ Note the direction taken when the robber leaves.
- ♦ Lock the pharmacy and store when the robber leaves.
- ♦ Try to get the description of the vehicle used in the getaway without compromising your safety.
- ♦ Be a good witness, and do not attempt to apprehend the robber.

Frequently Asked Questions

1. Where can Board registrants/licensees find the Guam pharmacy laws, rules, and regulations?

Health Professional Licensing Office

Marlene Carbullido, Acting Administrator
marlene.carbullido@dphss.guam.gov

123 Chalan Kareta
Mangilao, Guam 96913-6304

Tel: 671/735-7406
Fax: 671/735-7413

Online:

- ♦ Guam Pharmacy Practice Act: Article 6 of Chapter 12, Medical Practices, Title 10 Guam Code Annotated (GCA) Health and Safety
  www.guamcourts.org/CompilerofLaws/GCA/title10.html
- ♦ Guam Administrative Rules (GAR), Chapter 13, Guam Board of Examiners for Pharmacy, Title 25, GAR Professional and Vocational Regulations
  www.guamcourts.org/CompilerofLaws/GAR/025gar.html
- ♦ Guam Uniform Controlled Substances Act: Chapter 67, Title 9 GCA Crimes & Corrections
  www.guamcourts.org/CompilerofLaws/GCA/title9.html
- ♦ Guam Uniform Controlled Substances Act: Chapter 67, Title 9 GCA Crimes & Corrections, §67.401.2.3. Pseudoephedrine: Retail Sale
  www.guamcourts.org/CompilerofLaws/GCA/title9.html
- ♦ United States Department of Justice, Drug Enforcement Administration *Pharmacist's Manual*
  www.deadiversion.usdoj.gov/pubs/manuals/pharm2

2. Where can I find an application for licensure?

Health Professional Licensing Office
194 Hernan Cortez Ave, Second floor
Terlaje Professional Building
Hagatna, Guam

3. When and why does the Board do inspections?

10 GCA Chapter 12.12617. Powers and Responsibilities

(a)(12) inspection of any licensed person at all reasonable hours for the purpose of determining if any provisions of the laws governing the legal distribution of drugs or devices or the practice of pharmacy are being violated. (The Board of Pharmacy, its officers, inspectors and representatives shall cooperate with all agencies charged with the enforcement of the laws of the United States, of Guam and of all other states relating to drugs, devices, and the practice of pharmacy)

4. How can I prepare for an inspection?

The Board is updating the retail pharmacy inspection form, and it will be available in the near future.

The Board has an institutional pharmacy inspection form available for hospital, home infusion, and other institutional pharmacies.

5. Where is information on how patients should dispose of their medications?

- ♦ US Food and Drug Administration Safe Disposal of Medicines
  www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/default.htm
- ♦ US Environmental Protection Agency How to Dispose of Medicines Properly
  http://water.epa.gov/scitech/swguidance/ppcp/upload/ppcpflyer.pdf

Board Accepting Early Renewal Filings

In February 2015, the Board began accepting early renewal applications for the following licenses: registered pharmacist, registered pharmacist intern, registered certified pharmacy technician, registered technician, phar-

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macy outlet, and wholesaler with an expiration date of September 30, 2015. Registrants are encouraged to file their renewals early to avoid the large influx during the last quarter of the year. The new licenses, which will bear the expiration dates of September 30, 2016 for outlets and September 30, 2017 for individual registrants, will be released following the first, second, and third quarter Board meetings. Registrants are also urged to fill out and sign all items on the form correctly and completely in order to avoid returns due to incomplete forms. Continuing education hours (30 for pharmacists; 20 for technicians) must be earned during the period of October 2013 through September 2015 in order to be credited. For more information, contact the Board office.

Guam Prescription Drug Monitoring Program

The Guam Prescription Drug Monitoring Program (GPDMP) was established pursuant to Chapter 67, Title 9 GCA, Guam Uniform Controlled Substances Act, which mandates the Guam Department of Public Health and Social Services to administer this act to regulate the manufacture, distribution, and dispensing of pharmaceutical CS. The *Rules and Regulations for Guam Prescription Drug Monitoring Program* were put into effect when Governor Eddie Baza Calvo signed Public Law 31-272 on December 26, 2012.

All pharmacies that dispense CS should register with the GPDMP. The following information may be posted outside the pharmacy in public view: "This pharmacy participates in the online Guam Prescription Drug Monitoring Program. The system collects prescription data on ALL Scheduled controlled substances dispensed in Guam to identify possible abuse."

Information about the GPDMP may be found online at *http://dphss.guam.gov/content/prescription-drug-monitoring-program.* You may also contact Ms Cynthia Naval at cynthia.naval@dphss.guam.gov for further information.

Flonase Allergy Relief Is an OTC Drug

In 2015, Flonase® Allergy Relief was made available over-the-counter (OTC). This is the same as the prescription version, which will be discontinued. Insurance coverage may vary, and patients should contact their insurance carrier for further information. Flonase OTC will compete with Nasacort® Allergy 24HR, which has been on the OTC market since February 2014. Although Flonase OTC is indicated for both nasal and eye allergies, Nasacort is only indicated for nasal allergies, but will likely be effective for both symptoms as well.

Both are corticosteroids, which have potent anti-inflammatory effects due to a wide range of actions on mast cells, eosinophils, neutrophils, macrophages, and lymphocytes. They also affect the mediators of these cells that are involved in inflammation, including histamine, eicosanoids, leukotrienes, and cytokines. The therapeutic effects of corticosteroids are due to their topical effects on the nasal mucosa. Intranasal steroids can provide significant relief when they are used either continuously or as needed.

These corticosteroids are usually more effective than even combined use of oral antihistamines plus leukotriene inhibitors, and at least as effective as or more effective than intranasal antihistamines for nasal symptoms. Intranasal corticosteroids are the first-line option for treating moderate to severe or persistent allergic rhinitis. The most common side effects from using intranasal corticosteroids are nasal irritation and bleeding.

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