May 2019

Guam Board of Examiners for Pharmacy News

Published to promote compliance of pharmacy and drug law

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

Duty to Counsel

The Guam Board of Examiners for Pharmacy recently received a request for clarification regarding the pharmacist's duty to counsel, and whether technicians are able to verbalize this request and accept refusals. The two laws that deal with this issue are the federal mandate detailed in the Omnibus Reconciliation Act of 1990 (OBRA-90) and 25 Guam Administrative Rules (GAR) §13108 (a)(1)(v).

The portion of OBRA-90 applicable to patient counseling requires that states establish standards for counseling as part of their drug use review program. The requirement to counsel specifies that:

> The pharmacist must offer to discuss with each individual receiving benefits under this title or caregiver of such individual . . . who presents a prescription, matters which in the exercise of the pharmacist's professional judgment . . . the pharmacist deems significant . . .

A list of suggested topics to include in the consultation are listed in this portion of OBRA-90.

25 GAR §13108 (a) outlines the minimum procedures for compounding and dispensing, and 25 GAR §13108 (a)(1)(v) states that the pharmacist shall:

> Transfer the prescription to the patient or agent of the patient and give the patient or agent appropriate consultation relative to the prescription . . .

The Board believes that the language in this legislation is very clear. The intention is for the pharmacist (rather than the technician) to make the offer to counsel. If the offer is declined, the pharmacist should document this on the prescription or consultation log either as a hard copy or electronically. The Board encourages pharmacists to embrace their role as providers and use their unique skills to improve the pharmaceutical care of their patients.

USP General Chapter <795> Pharmaceutical Compounding—Nonsterile Preparations

Since the 2012 fungal meningitis outbreak from compounded preparations made by the New England Compounding Center, there have been some changes in federal law. One of the major changes was the addition of Section 503A to the Federal Food, Drug, and Cosmetic Act (FD&C Act). This specified the separation of compounding pharmacies that practice compounding within the confines of a specific order for a patient. In contrast, Section 503B of the FD&C Act distinguished pharmacies that act as outsourcing facilities that produce larger quantities for use in facilities. However, both sections require pharmacies to comply with United States Pharmacopeia (USP) General Chapters <795> and <797>.

USP General Chapter <795> deals with the pharmaceutical compounding of nonsterile preparations. The responsibilities of the compounder include: using quality ingredients from reliable sources that meet the standards of chemicals used, appropriate training for those involved, and appropriate documentation of activities relating to the process, including training of the personnel involved. Assigning an appropriate beyond use date (BUD) is also explained in the section as no later than 14 days for oral formulations containing water and six months for nonaqueous formulations (earlier if the manufacturer's date of any ingredient is less). Each compound shall come from a master formulation record with specific instructions on how to prepare the formulation, which is followed each time the same preparation is made. Each formulation shall be recorded and include, but is not limited to, the following information:

- name
- strength
- dosage form

Continued on page 4

National Pharmacy Compliance News

May 2019

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.

FDA Launches Pilot Program to Improve Security of Drug Supply Chain With an Innovative Approach

Food and Drug Administration (FDA) has launched a pilot program allowing participants representing the various parts of the drug supply chain to pilot innovative and emerging approaches for enhanced tracing and verification of prescription drugs in the United States' supply chain. The program is in line with FDA's ongoing efforts to prevent suspect and illegitimate products from entering the supply chain, according to an FDA press release. Eligible manufacturers, repackagers, and other stakeholders can apply to participate in the program, which will inform the development of the enhanced electronic, interoperable track-and-trace system for industry set to go into effect in 2023 in accordance with the Drug Supply Chain Security Act (DSCSA), enacted by Congress on November 27, 2013.

The pilot technologies of this program may become part of FDA's enhanced expectations for reliable track-and-trace systems, which will be designed to reduce diversion of drugs distributed domestically and to keep counterfeit drugs from entering the supply chain. The DSCSA pilot project program is intended to help identify and evaluate the most efficient processes to comply with and apply drug supply chain security requirements and will aid in identifying attributes the system will need for enhanced product tracing and verification, as well as electronic means to share the information. FDA recently issued draft guidance on the use of product identifiers with a unique serial number to improve verification down to the package level. FDA has also provided draft guidance for verification systems to quarantine and investigate suspect and illegitimate drugs.

Additional information on the FDA pilot program is available in a February 8, 2019 announcement in the *Federal Register.*

FDA Announces New Efforts to Increase Oversight and Strengthen Regulation of Dietary Supplements

Noting that three in four Americans now take at least one dietary supplement on a regular basis, and that the dietary supplement industry has expanded to include as many as 80,000 different products for consumers, FDA Commissioner Scott Gottlieb, MD, has announced new plans to increase the agency's oversight of dietary supplements. These initiatives include communicating to the public as soon as possible when there is a concern about a dietary supplement on the market, ensuring that the regulatory framework is flexible enough to adequately evaluate product safety, and continuing to work closely with industry partners. FDA is also developing new enforcement strategies to respond to entities that violate standards established under the Dietary Supplement Health and Education Act of 1994.

On February 11, 2019, FDA sent 12 warning letters and five online advisory letters to foreign and domestic companies that are illegally selling more than 58 products. The products are illegally marketed as unapproved new drugs that make unproven claims about preventing, treating, or curing Alzheimer's disease, as well as a number of other serious diseases and health conditions, such as diabetes and cancer. In his statement, Gottlieb noted that most stakeholders in the industry act responsibly, but he expressed concern over the ability of bad actors to exploit the system by providing potentially dangerous products and making unproven or misleading claims about the health benefits supplements may offer.

FDA is planning a public meeting on this topic during the second quarter of 2019. For more information, view the FDA statement at *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm631065.htm.*

Trump Administration Releases National Drug Control Strategy to Reduce Drug Trafficking and Abuse

As the opioid crisis continues to claim the lives of tens of thousands of Americans each year, the Office of National Drug Control Policy has released its *National Drug Control Strategy.* The *Strategy* breaks down the administration's priorities in addressing the crisis, with an emphasis on three areas: prevention, treatment and recovery, and reducing availability.

- **Prevention** efforts are focused on educating both consumers and caregivers about the dangers of opioid misuse and include a new national media campaign, continued efforts to expand prescription monitoring programs (PMPs), and improving the ability of state, local, and tribal communities to identify and prevent substance abuse.
- **Treatment and recovery recommendations** in the *Strategy* include improving access to naloxone, improving evidence-based addiction treatment, and eliminating barriers for accessing treatment.

- **Reducing availability** strategies are focused on disrupting illegal supply chains, defeating drug traffickers, increased cooperation with international partners, and combating illegal internet drug sales.

The document notes that the "most important criterion of success" is saving lives and calls for the federal government to work closely with state and local governments, as well as other stakeholders. Additional information, including the full strategy document, is available on the White House website at *https://www.whitehouse.gov/opioids.*

National Association of Boards of Pharmacy® (NABP®) and its member boards of pharmacy remain committed to advancing best practices for PMPs in the interest of public health. NABP's PMP data sharing system, NABP PMP InterConnect®, facilitates the secure transfer of PMP data across state lines and provides an effective means of combating drug diversion and drug abuse nationwide. In addition, NABP and its member boards continue efforts to educate consumers about prescription drug safety. The NABP AWAR$_X$E® Prescription Drug Safety Program's Drug Disposal Locator Tool has more than 6,000 disposal locations and continues to add new locations to provide consumers with a safe way to dispose of medication and help prevent misuse and abuse of prescription medications. For more information about PMP InterConnect and the AWAR$_X$E program, visit the Initiatives section of the NABP website at *www.nabp.pharmacy.*

New Study Predicts Opioid Epidemic Will Worsen Over the Next Decade

More than 700,000 people will die from opioid overdoses between 2016 and 2025, and annual overdose deaths will reach nearly 82,000 by 2025, estimates a new study published to *JAMA Network Open.* The estimate is based on an analysis of data from the National Survey on Drug Use and Health and the Centers for Disease Control and Prevention from 2002 to 2015.

Researchers also projected that intervention efforts focused on lowering the incidence of prescription opioid misuse would help to reduce the number of deaths 3.8% to 5.3%, a figure the researchers described as "modest," due to the changing nature of the opioid crisis. The study notes that more people are directly initiating opioid use with illicit opioids rather than prescription drugs, and illicit opioids have become more lethal with the availability of illegally manufactured fentanyl.

The researchers encourage policymakers to take "a stronger and multipronged approach" to reduce the impact of the ongoing opioid overdose epidemic. The full article is available at *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723405.*

FDA Warns of Potential Blood Pressure Medication Shortages Due to Recalls

FDA is warning health care providers and consumers of a shortage of angiotensin II receptor blockers, commonly used to treat high blood pressure. A growing list of medications containing valsartan, losartan, and irbesartan have been recalled from the market for containing an impurity that may present a cancer risk to patients. The issue was first detected in the summer of 2018, according to a statement posted to the FDA website. Since then, FDA has placed a Chinese manufacturer of the active ingredient on import alert to stop their imports, and FDA is working with other manufacturers to recall affected medications.

In the statement, FDA notes that the risk to individual patients remains very small, but that there is still reason to be concerned about the potential health risks. Medications with these impurities are believed to have been in the market for about four years.

"Now that these risks are identified, we're applying what we've learned to the evaluation of similar manufacturing processes where we now know these risks could arise," the statement notes. The FDA press release is available at *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm629796.htm.*

FDA Releases Two Draft Guidances Related to REMS Programs

FDA has released two new draft guidances to ensure risk mitigation programs put in place for certain drugs and biologics, as required for approval, are working. The agency's primary risk management tool is FDA-approved product labeling. However, in limited cases, FDA may require a Risk Evaluation and Mitigation Strategy (REMS) to help ensure a drug's benefits outweigh its risks.

The following guidances relate to the assessment of REMS programs:

- **REMS Assessment: Planning and Reporting Guidance for Industry** describes how to develop a REMS Assessment Plan.
- **Survey Methodologies to Assess REMS Goals That Relate to Knowledge Guidance for Industry** provides recommendations on conducting REMS assessment surveys to evaluate patient or health care provider knowledge of REMS-related information.

FDA states that the goal in providing this guidance for REMS is to ensure constant improvement of their safety programs and establish the most efficient and effective programs moving forward, to optimize patient care and keep consumers safe and healthy. More information on REMS is available on the FDA website at *https://www.fda.gov/drugs/drugsafety/rems.*

Continued from page 1

- lot numbers of all ingredients
- expiration dates of all ingredients
- the personnel who prepared and approved the compounded preparation

Additionally, the equipment used shall be clean, properly maintained, and used appropriately.

It is the responsibility of the compounder to ensure that those involved in preparing nonsterile compounds receive proper training and annual evaluations.

Personnel labeling nonsterile compounds shall follow all state and federal laws, include the BUD and storage instructions, and indicate that "this is a compounded preparation."

Guam law states that compounding includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine and regularly observed prescribing patterns. This is supported by Section 503A, which states that a compounder "does not compound regularly or in inordinate amounts (as defined by the [United States Secretary of Health and Human Services]) any drug products that are essentially copies of a commercially available drug product." Once compounders deviate from compounding a specific order for a specific patient, Food and Drug Administration requires registering as an outsourcing facility or manufacturer.

Please refer to USP General Chapter <795> for details on nonsterile compounding, in addition to Section 503A for further guidance.

CSR Not Required for Pharmacists

The Guam Department of Public Health and Social Services (DPHSS) Division of Environmental Health enacted updated rules regarding controlled substances in January 2018. More specifically, the Rules Governing the Manufacture, Distribution, and Dispensing of Controlled Substances, 26 GAR, Division 1, Chapter 4, Article 16 were updated. The Board has been asked to clarify whether a Guam controlled substance registration (CSR) is required for pharmacists. Linda DeNorcey, director of DPHSS, has clarified that pharmacists are not required to obtain a CSR.

Pharmacy Practice Reminder

According to 25 GAR §13108:

> A pharmacist may supervise no more than one pharmacy intern and one non-pharmacist engaged in compounding and dispensing activities . . . a higher ratio may be authorized by the Board upon request to and approval by the Board of a specific plan describing the manner in which additional interns or non-pharmacists shall be supervised.

Please submit requests in writing for Board approval.

Deadline for Renewal Applications

Renewal applications are due on **September 30, 2019,** for the following registrants:

- Facilities (wholesale distributor)
- Pharmacies (resident and nonresident)
- Pharmacists **(continuing education requirements apply)**
- Pharmacy technicians

Pharmacy interns must renew by **July 1, 2019.**

You may visit the Health Professional Licensing Office at the Terlaje Building in Hagåtña, Guam, for an application, or send a written request to the Board (via mail, fax, or email) with the registrant's name, permit or license number, and mailing address, along with a request for application form, which will be sent via mail. Submit the application form with the appropriate fee using a check or money order to the office of the Treasurer of Guam.

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