



Guam Board of Examiners for Pharmacy

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Expansion of Pharmacy Technician Roles

The pharmacy profession has seen an increased expansion of both pharmacists' and technicians' roles in recent years. Pharmacists' responsibilities have shifted to more direct patient care, drug level monitoring, protocol and policy development, and participation in interdisciplinary teams. As a result, this shift has affected pharmacy technician roles and duties to include many new tasks that include taking medication histories, performing medication reconciliation, administering vaccines, managing inventory, and performing nonsterile and sterile compounding.

In Idaho, qualified, trained pharmacy technicians are allowed to administer vaccines under the supervision of a pharmacist. In at least 14 states, pharmacy technician final verification (tech-check-tech) is permitted in health systems, and in at least nine states, this is permitted in the community setting. Expanding roles of technicians has also been acknowledged and supported by the National Association of Boards of Pharmacy® (NABP®), Pharmacy Technician Certification Board (PTCB), and The Joint Commission.

During the 115th NABP Annual Meeting in May 2019, delegates from member boards of pharmacy voted to adopt Resolution 115-4-19 to establish a Task Force on Requirements for Technician Education, Practice Responsibilities, and Competence Assessment. Additionally, PTCB has created additional certification programs focused on specialized skills, including certified compounded sterile preparation technician, technician product verification certificate, and the medication history certificate. With the medication history certificate, technicians have specialized knowledge to perform in-depth medication histories, identify potential medication errors, and complete administrative duties related to medication reconciliation. Solidifying the importance of medication reconciliation is demonstrated through The Joint

Commission's move to add medication reconciliation across the care continuum as a national patient safety goal.

Medication reconciliation is "the process of comparing the medications a patient is taking (and should be taking) with newly ordered medication" in order to resolve discrepancies of potential problems.¹ This process is most important during hospital admissions and during transitions of care since more than 40% of medication errors may be the result of improper handoffs during admission, transfers, and discharge. Medication orders are based on medication histories and deserve proper attention to detail. Studies have shown that under a pharmacist's supervision, medication histories obtained by pharmacy technicians are significantly more accurate than those collected by other health care professionals.

One study of 300 medication histories showed that those conducted by pharmacy technicians were without errors 88% of the time compared with 57% conducted by nurses. It was also shown that 1.1% (19 out of 1,727) of errors were from pharmacy technicians compared to 8.3% (117 out of 1,410) by nurses. Additionally, high-risk anticoagulant and antiplatelet administration times were documented 76% of the time by pharmacy technicians compared with 13% of the time by nurses.² Another study involving pharmacy technician-involved medication histories showed a 27% reduction in readmission rates.³

The logistical process of a medication reconciliation encounter is nonjudgmental and can be adequately performed by a trained pharmacy technician. Skilled pharmacy technicians are in the perfect position to perform safe and efficient medication histories because they have baseline knowledge of prescription medications, familiarity of brand and generic names and dosage strengths and forms, good interpersonal communication skills, familiarity of community pharmacy practices, and work closely with pharmacists.

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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 Proposes New Regulations to Address Opioid Epidemic

Drug Enforcement Administration (DEA) has announced proposed regulations to improve the agency's ability to oversee the production of opioids and other potentially dangerous drugs. The proposed regulation would further limit the quantities of medications that might be vulnerable to diversion and misuse. The proposal would also amend the manner in which DEA grants quotas to certain registered manufacturers to levels aligned with current manufacturing standards aimed at promoting quality and efficiency while also ensuring the country has sufficient quantities of Schedule II controlled substances (CS) necessary for medical, scientific, research, and industrial needs.

The proposal introduces several new types of quotas that DEA would grant to certain DEA-registered manufacturers. These use-specific quotas include quantities of CS for use in commercial sales, product development, packaging/repackaging and labeling/relabeling, or replacement for quantities destroyed. These quotas are intended to improve DEA's ability to respond quickly to drug shortages.

The proposed changes build on 2018 regulatory changes that gave a role to state attorney generals and other federal agencies in setting the aggregate production quotas for Schedule I and II CS. The proposed regulations are available in the October 23, 2019, *Federal Register* announcement at <https://www.federalregister.gov/documents/2019/10/23/2019-21989/management-of-quotas-for-controlled-substances-and-list-i-chemicals>.

FDA Issues Report on Root Causes and Solutions to Drug Shortages

Food and Drug Administration (FDA) has released a new report, *Drug Shortages: Root Causes and Potential Solutions*, which identifies root causes for drug shortages and recommends three "enduring solutions" to address the shortages. These recommendations include:

- ◆ creating a shared understanding of the impact of drug shortages on patients and the contracting practices that may contribute to shortages;
- ◆ developing a rating system to incentivize drug manufacturers to invest in quality management maturity for their facilities; and
- ◆ promoting sustainable private sector contracts (eg, with payers, purchasers, and group purchasing orga-

nizations) to make sure there is a reliable supply of medically important drugs.

In addition to these recommendations, the report outlines the agency's ongoing initiatives to mitigate drug shortages and legislative proposals in President Donald J. Trump's Fiscal Year 2020 budget. FDA also highlighted the need for international action, including global implementation of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use's (ICH's) *ICH Guideline Q12: Technical and Regulatory Consideration for Pharmaceutical Product Lifecycle Management*, which provides opportunities for regulatory flexibility in making post-approval changes to the product or its manufacturing process.

"We hope that the recommendations set forth in this report will help to set a framework that all stakeholders can assess and implement as we work together to further mitigate the public health impact that drug shortages have on American consumers," FDA stated. "In the meantime, the FDA's employees remain committed to working behind-the-scenes to anticipate and help mitigate shortages and make sure that patients have access to the drugs they need."

FDA's full statement is available at <https://www.fda.gov/news-events/press-announcements/statement-fdas-new-report-regarding-root-causes-and-potential-solutions-drug-shortages>.

HHS Announces Guide for Appropriate Tapering or Discontinuation of Long-Term Opioid Use

The United States Department of Health and Human Services (HHS) has published a new guide for clinicians intended to provide guidelines for tapering or discontinuing long-term opioid use. The guide, titled *HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics*, covers important issues to consider when changing a patient's chronic pain therapy. The guide also lists issues to consider prior to making a change, when initiating the change, and as a patient's dosage is being tapered, including the need to treat symptoms of opioid withdrawal and provide behavioral health support.

"Care must be a patient-centered experience. We need to treat people with compassion, and emphasize personalized care tailored to the specific circumstances and unique needs

of each patient,” said ADM Brett P. Giroir, MD, assistant secretary for health in a press release. “This Guide provides more resources for clinicians to best help patients achieve the dual goals of effective pain management and reduction in the risk for addiction.”

FDA Releases Draft Best Practice Document for Postmarket Drug Surveillance

As part of FDA’s efforts to enhance the efficiency of its postmarket drug safety surveillance, the agency has released a new best practices document, *Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff*. The draft document outlines FDA’s approach for timely postmarket analyses of drugs and biologics, and includes a high-level overview of tools, methods, and signal detection and evaluation activities, using varied data sources, for drug safety. The goal is to provide a broader context and a general overview of ongoing efforts and commitments.

“Our best practices document incorporates the guiding principle that postmarket safety surveillance is a dynamic and constantly evolving field,” FDA said in a statement announcing the document’s release. “By using a risk-based approach, the FDA takes into account the nature of the drug, its potential adverse events, the intended population, and the potential for serious outcomes, as well as the impact on individuals and the overall potential impact on the health of the public.”

The full draft document can be accessed at <https://www.fda.gov/media/130216/download>.

FDA Issues Revised Draft Guidance on Regulation of Homeopathic Products, Withdraws 1988 Compliance Policy Guide

FDA is taking two new steps to clarifying their approach to regulating drug products labeled as homeopathic: revising draft guidance previously published in 2017, and withdrawing the Compliance Policy Guide (CPG) 400.400 issued in 1988. These moves were announced in a statement published on the FDA website. Homeopathic products are often marketed as natural alternatives to approved prescription and nonprescription products and are widely available in the marketplace. Homeopathic products, however, are marketed without FDA review and may not meet modern standards for safety, effectivity, quality, and labeling. FDA uses a risk-based approach to monitor these products and to evaluate reports of adverse events.

The revisions to the 2017 draft guidance provide further information about FDA’s approach. The guidance details a risk-based enforcement policy prioritizing certain categories of homeopathic products that could pose a higher risk to public health. These include products with particular ingredients and routes of administration, products for vulnerable populations, and products with significant quality issues. FDA has invited public comment on the guidance before it is finalized. The full guidance and instructions for providing comment are available in the *Federal Register* announcement.

CPG 400.400, *Conditions Under which Homeopathic Drugs May be Marketed*, is being withdrawn due to inconsistency with the agency’s risk-based approach to regulatory and enforcement action and is therefore being withdrawn. Specifically, FDA states that it has encountered multiple issues with homeopathic drug products posing significant risk to patients, even though the products, as labeled, appeared to meet the conditions of CPG 400.400.

DEA Warns of Increase in Scam Calls Targeting Pharmacists and Other DEA-Registered Providers

DEA is warning health care providers and other members of the public of another increase in fraudulent phone calls attempting to extort money. Though the tactics change regularly, the callers typically claim to represent DEA and provide either fake names and badge numbers, or the names of well-known senior officials with DEA. The scammers then threaten legal action, including arrest, against the victim unless large fines are paid by wire transfer. Most recently, the scammers appear to be spoofing a DEA number based out of Salt Lake City, UT, according to a DEA press release.

The agency emphasizes that DEA will never contact practitioners by phone to demand money or any form of payment. DEA will not request any personal or sensitive information by phone, and notification of a legitimate investigation or legal action is always made via official letter or in person.

DEA asks anyone who receives a call from a person purporting to be a DEA special agent or other law enforcement official asking for money to refuse the demand and report the threat using the online form or by calling 877/792-2873. Reporting these calls will assist DEA in investigating and stopping this activity.

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General Announcements

Board Welcomes New Staff Member

The Guam Board of Examiners for Pharmacy would like to welcome Marie B. Baleto-Sherwin. She is our new administrative assistant dedicated to the Board. Marie has been with the Health Professional Licensing Office since October 2019, previously working under the Bureau of Family Health and Nursing Services since 2015. Marie has worked in the administrative field for numerous years, beginning in Seattle, WA, where she was raised and eventually met her husband, Douglas Sherwin. They have a daughter, Danielle, who currently resides in Seattle and works for the CenturyLink and T-Mobile parks. Marie may be contacted by phone at 671/735-7408 or by email at marie.baleto-sherwin@dphss.guam.gov.

The Health Professional Licensing Office Mailing Address Has Changed to:

194 Hernan Cortez Ave, Terlaje Professional Building, Ste 213, Hagatna, GU 96910. Please update your records to reflect this change.

From the Chair

For those of you who do not know, Guam is a not-too-small United States territorial island in the Western Pacific, closer to Japan and the Philippines than even to Hawaii. We have 30 retail, three public health, two IV infusion, and two hospital (one private and one public) pharmacies. There is also one Air Force and one Navy pharmacy, which we have no authority over. Until just three years ago, all pharmacies

were inspected when they opened, and not since! With the help of pharmacist Board members Vangie Phillips, Angie Eustaquio, Racquel Sperrazzo, Gary Roy, and two volunteer inspectors, Eva Aguon and Maggie Greenwood, the Board started inspections of local pharmacies for the first time in many years, and in some cases, decades!

The key to our success in starting routine inspections was getting Board members who wanted to make a change and improve the island's pharmacies and the pharmacy profession. With the help of those previously mentioned, we have now inspected all pharmacies at least twice. For the most part, pharmacies were run pretty well. However, we did find some areas that needed improvement. We found some pharmacies selling "gray market" goods, ie, products that were the same as US products, but that had no National Drug Code numbers, and some with instructions in a foreign language. We also discovered the sale of a US product that was exclusive to a US outlet while there were no contracts in place for the sale of those products on Guam. The most egregious violation had to do with a pharmacy owner being off the island while their pharmacy was being run by unlicensed personnel. I do believe we have turned things around.

The current Board has had an immediate and, we hope, a lasting impact on the profession of pharmacy on our island of Guam. Being so far removed from the US mainland is no excuse for not doing the right thing. We hope you will continue to improve the island's health care by joining us in making the people of Guam our top priority.

Jerry Caruso
Board Chairman

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