

From: Klein, Fara]
Sent: Friday, September 16, 2016 9:36 AM
To: Gay Dodson < >
Subject: USP

Dear Gay Dodson,

Our organizations are writing today in regards to a new general chapter from the U.S. Pharmacopeial Convention (USP), *General Chapter <800>, Hazardous Drugs—Handling in Healthcare Settings*. The purpose of the chapter, per USP, is “to describe practice and quality standards for handling hazardous drugs in healthcare settings and help promote patient safety, worker safety, and environmental protection.”

Chapter <800> will apply to all healthcare personnel who handle hazardous drug preparations, including members of our organizations. Also impacted will be nurses, physicians, physician assistants, home healthcare workers, veterinarians, and veterinary technicians and the entities where they practice.

General Chapter <800> utilizes the National Institute for Occupational Safety and Health (NIOSH) list of antineoplastic and other hazardous drugs to define a hazardous drug preparation. There are multiple commonly dispensed drugs on this list, including estrogen and progestin containing drugs, anticonvulsants, immunosuppressive agents, antifungal agents, atypical antipsychotics and warfarin. The impact of General Chapter <800> on our members is substantial from both an economic and operational perspective and compliance with the new general chapter will require changes such as the use of Personal Protective Equipment (PPE) and the potential for reconstruction of facilities.

General Chapter <800> was published on February 1, 2016. In recognizing that it will take facilities time to conform to the new requirements, USP extended the official implementation date until July 1, 2018. However, given such highly complex, resource intensive, and time consuming compliance requirements, we respectfully request that the Texas State Board of Pharmacy carefully consider any actions related to pharmacy compliance with the standards.

Employee safety must always be a top priority. Our members are currently held to and comply with regulations and guidelines from entities such as the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), and The Joint Commission (TJC), which detail the handling of hazardous material that serve to protect employees. We appreciate the intent of the proposed chapter <800>, however, the impact on our members and their patients in relation to a 2018 enforcement date is too great at this time and full compliance would be extremely difficult to the vast majority of our members.

In order to give our members the opportunity to perform the proper analyses, including budget implications and the impact upon the delivery of services to patients, and to fully integrate General Chapter <800> into their practice settings, we feel that a delay in enforcement is warranted, similar to the phased in approach that accompanied the introduction of USP *General Chapter <797> Pharmaceutical Compounding – Sterile*.

A delay in enforcement of USP <800> allows healthcare organizations sufficient time to plan and gradually implement changes. Budgeting capital expenses is a multistep, multi-year process that is not under the control of many pharmacies. Some organizations may have to justify their <800> project proposal to numerous organizational stakeholders, spread expenditures over more than one budget cycle, and integrate their project into existing organizational project timelines.

If the Texas State Board of Pharmacy agrees that a graduated approach to implementing General Chapter <800> is consistent with its mission and goals, we respectfully request that the Texas State Board of Pharmacy grant a five year delay in enforcement of General Chapter <800> until July 1, 2021. This grace period allows state-licensed practitioners to assess and plan for the significant operational and structural changes needed as well as budget and obtain the necessary resources in an already strained financial environment.

We appreciate your thoughtful consideration of our comments regarding *General Chapter <800>, Hazardous Drugs—Handling in Healthcare Settings*.

Sincerely,

American Pharmacists Association (APhA)
American Society of Consultant Pharmacists (ASCP)
College of Psychiatric and Neurologic Pharmacists (CPNP)
International Academy of Compounding Pharmacists (IACP)
National Alliance of State Pharmacy Associations (NASPA)
National Association of Chain Drug Stores (NACDS)
National Community Pharmacists Association (NCPA)