

RESOLUTIONS AS SUBMITTED TO NABP

District 2

Lyophilization and Compounding (co-supported by District 1)

Whereas, some compounding pharmacies are performing lyophilization which may pose risks when compounding under USP standards, and

Whereas, some compounding pharmacies are adding a second ingredient to a compounded drug which may not produce a clinical significance for the patient and may be intended to circumvent federal prohibitions for compounding inordinate amounts of drug of essential copies of a manufactured drug, and

Whereas, the patient demand for these compounded drugs which are often priced lower than manufactured drugs may be creating a financial incentive for pharmacies to compound these drugs which increases the prevalence of this issue,

Therefore, be it resolved that NABP work with FDA and USP to clarify federal prohibitions for compounding essential copies of drug and under what circumstances, if any, a pharmacy may perform lyophilization, and to amend the model law and regulations as necessary.

Public Access to Vaccination Services by Pharmacy Personnel

Whereas, Pharmacists, pharmacy technicians, and pharmacy interns play a critical role in delivering timely, accessible, and reliable vaccination services to the public.

Whereas, in many states, the authority for pharmacists, pharmacy technicians, and pharmacy interns to administer vaccines is tied directly to recommendations from federal bodies such as the CDC, (ACIP), and/or FDA.

Whereas, as federal processes evolve, recommendations change, and advisory structures shift; such references can create unintended legal and regulatory ambiguity, reduce flexibility, and delay access to newly authorized vaccines.

Therefore be it resolved, that NABP create model language that pharmacists should be authorized to prescribe/order and administer all vaccines and should be permitted to delegate administration of all vaccines to pharmacy technicians and pharmacy interns under the supervision of a pharmacist; encourage states to adopt standard-of-care and evidence-based approaches that empower pharmacists' clinical judgment; and define eligible vaccines as any vaccine.

Blueprint Resolution

Whereas, some Boards of Pharmacy delayed enforcement of recent revisions of USP compounding standards for various reasons, and

Whereas, there is inconsistency with compounding standards across the states which may place patients at risk of harm and result in pharmacy noncompliance across the states, and

Whereas, NABP created the Uniform Inspection Blueprint in 2013 to create agreed upon expectations for states inspecting compounding pharmacies to ensure compliance and patient safety,

Therefore, be it resolved that NABP convene a workgroup to review the uniform blueprint inspection report to ensure it fully complies with USP standards, can be completed by state inspectors within a reasonable amount of time, and ensure that participating blueprint states are fully inspecting for compliance with USP compounding standards.

Virtual Facilities

Whereas, virtual manufacturers and virtual wholesale distributors are becoming more prevalent, and

Whereas, only 11 states have a virtual-specific license category, 17 states have a Virtual-friendly application for a manufacturer or wholesaler license, 8 states have a manufacturer or wholesaler application that does not consider their differences, and 14 States consider virtuals exempt, and

Whereas the NABP model laws do not distinguish between the standards for a virtual facility compared to a traditional facility that physically possesses drug, and

Whereas a designated representative is not required to be licensed but does assume responsibility for ensuring compliance and mitigating risks with diversion and counterfeit activities,

Therefore, be it resolved that NABP convene a workgroup to recommend amendments to the model law and regulations to create a virtual-specific license for manufacturers and wholesale distributors, develop specific requirements that are appropriate for a facility that does not physically possess drug, and consider whether the designated representative should be licensed.

District 6

Community Health Workers

WHEREAS, state boards of pharmacy are charged with protecting the public health, safety, and welfare through the regulation of pharmacy practice and services;

WHEREAS, pharmacy technicians are an integral component of pharmacy practice;

WHEREAS, the United States Center for Disease Control and Prevention defines a Community Health Worker (CHW) as *“a frontline public health worker who lives in or is trusted by the community”* and *“connects people to health and social services by breaking down barriers related to the social determinants of health”*;

WHEREAS, the American Public Health Association has determined *“this trusting relationship”* between CHWs and the community *“enables CHWs to serve as a liaison/link/intermediary between health/social services and the community to facilitate access to services and improve the quality and cultural competence of service delivery. CHWs also build individual and community capacity by increasing health knowledge and self-sufficiency through a range of activities such as outreach, community education, informal counseling, social support and advocacy”* (APHA Support for Community Health Workers to Increase Health Access and to Reduce Health Inequities (2009));

WHEREAS, the Center for Medicare and Medicare Services (CMS) has determined CHWs can also “help health care organizations improve health care quality [and] reduce provider burden” (See *“On the Front Lines of Health Equity: Community Health Workers (2021)”*);

WHEREAS, CMS has further determined CHWs play “an integral role in helping healthcare organizations achieve health equity. . . especially within organizations that aim to support vulnerable patients”;

WHEREAS, pharmacy technicians engaged as CHWs have a unique opportunity to assist pharmacists and members of the healthcare team in directly impacting health outcomes by addressing social barriers to care.

THEREFORE, BE IT RESOLVED that NABP encourage the adoption of Community Health Workers (CHWs) as critical support personnel in pharmacies to help address social determinants of health, health disparities and healthcare access inequities among patients and communities serviced.

BE IT FURTHER RESOLVED, that NABP encourage member boards review applicable law/regulations to remove unnecessary barriers to authorized pharmacy technician CHW activities, provided such activities are appropriately supervised to ensure activities are safely and properly performed.