

Pennsylvania Department of Health Pharmacy Pandemic Influenza Memorandum of Agreement Project

Authored by Joanne Roth, Public Health Program Manager, Bureau of Public Health Preparedness, Department of Health

The Pennsylvania Department of Health (DOH) Pandemic Influenza Memorandum of Agreement project began in March of 2016 when the National Association of Chain Drug Stores provided a grant opportunity for improving vaccination rates through community partnerships and technology. The University of Pittsburgh School of Pharmacy applied for the grant in collaboration with Giant Eagle Pharmacy, and with a DOH signed letter of support, received funding in July of 2016.

As part of this project, DOH worked with Giant Eagle Pharmacy to enroll them in and test the PA State Immunization and Information System (PA SIIS). PA SIIS is a database used by the DOH to track vaccination rates by vaccine providers. In March of 2017, Giant Eagle Pharmacy completed their testing of PA SIIS, and in April of 2017 they began reporting immunizations to PA SIIS.

Around the same time period, the University of Pittsburgh School of Pharmacy and Giant Eagle Pharmacy hosted a stakeholders' meeting. The meeting brought together public health and community pharmacy partners to expand the capacity to deliver pandemic vaccination through Pennsylvania community pharmacies. One of the goals of the meeting was to operationalize the Association of State and Territorial Health Officials (ASTHO) Pharmacy Pandemic Influenza Memorandum of Understanding in Pennsylvania. During the meeting there was consensus on moving forward with operationalizing the ASTHO MOU toolkit and template.

The DOH developed a draft Pharmacy Pandemic Influenza Memorandum of Agreement (MOA) and distributed it to stakeholders in September of 2017 for comment. The proposed MOA was finalized and introduced at the annual Pennsylvania Pharmacy Association meeting in January 2018.

In November of 2017, ASTHO provided a funding opportunity to assist in a project such as this. DOH applied and received funding for one statewide meeting and four regional meetings to operationalize the approved MOA.

On March 29, 2018, there was a statewide meeting in State College to engage the pharmacy community in pandemic and all-hazards planning. Attendees included the PA Pharmacy Association, Counsel for the PA State Pharmacy Board, Rite Aid, Giant Eagle, University of Pittsburgh and independent pharmacies. The meeting provided an opportunity for the DOH to gather valuable feedback to move forward with the project, and also for the various stakeholders to engage with one another.

Additional meetings were held from June through September in Wilkes Barre, Conshohocken and Pittsburgh. At the time of the final meeting in Pittsburgh, DOH

presented the draft Pharmacy MOA webpage for the DOH website. The feedback was positive, and the webpage went live on October 31, 2018.

The webpage can be accessed at <http://pharmacymoa.health.pa.gov> and questions or concerns may be directed to RA-DHPHARMACYMOA@pa.gov. The webpage contains information on the MOA and why coordination between public health agencies and pharmacies is important. Links to the MOA itself and other pertinent documents are also available, and we encourage pharmacies to participate in this initiative. DOH received several signed MOAs and has had discussions with Giant Eagle Pharmacy and Value Drug on completing the MOA process. Meetings with Rite Aid and Walgreens are being scheduled as well.

The ASTHO grant provided the opportunity for DOH to meet face-to-face with the statewide pharmacy community and engage them in supporting their community during a public health emergency. We appreciate the support from the pharmacy community on this initiative and look forward to the continued engagement.

Intern Hours Requirements

The Pennsylvania State Board of Pharmacy (Board) voted at a special meeting on June 28, 2018, to temporarily waive Board Regulation Sections 27.26(d)(3)-(4). This waiver removes the requirement that applicants with a Pharm.D. degree from a school of pharmacy accredited by the Accreditation Council for Pharmacy Education (ACPE) serve at least 500 of the 1,500 required hours in a pharmacy and outside of school. *This means that all 1,500 intern hours required for licensure may be earned through an ACPE-accredited Pharm.D. program.*

The Board is in the process of amending the Board Regulations to make this a permanent change. In the meantime, this waiver remains in effect until at least January 1, 2020.

Web Site Links: Did you Know....

The **scope of practice of an individual** is determined by the board that licenses that individual. Review the appropriate board's law and regulations for information - <https://www.dos.pa.gov/ProfessionalLicensing/BoardsCommissions/Pages/default.aspx>.

The **Medical Marijuana Program** is administered by the PA Department of Health - <https://www.health.pa.gov/topics/programs/Medical%20Marijuana/Pages/Medical%20Marijuana.aspx>.

The **Prescription Drug Monitoring Program** (PDMP) is administered by the PA Department of Health - <https://www.health.pa.gov/topics/programs/PDMP/Pages/PDMP.aspx>.

Verification of a license is available at www.pals.pa.gov/verify. For example, if you wish to confirm that your license was successfully renewed, you can search the verification web site using your name or license number to determine what your license expiration date is. Note: When searching the verification web site, be sure that you have marked the category that you wish to search (e.g., person, facility). It may be better to use *limited* search criteria (e.g., only a name or the license number) rather than completing numerous search fields.

If you require help navigating the new online **PALS** system, assistance is available on numerous topics at the Help Center - <https://www.pals.pa.gov/#/page/AnonymousSupportTicket>.

The Department of Health's **Drugs, Devices and Cosmetics (DDC) Program** oversees drug, medical device, and medical gas wholesalers, distributors and manufacturers. This includes, but is not limited to, traditional manufacturers, third party logistics, reverse distributors, repackagers, DMEs, and 503B outsourcing facilities. The DDC program mainly oversees the Pennsylvania Controlled Substance, Drug, Device and Cosmetic Law, the Pennsylvania Wholesale Drug Distributors License Law and related Regulations. The program has some limited oversight with the Pennsylvania Generic Equivalent Drug Law and the Noncontrolled Substance (List I chemical) Registration and Reporting Law. Interested parties may view the program website at <https://apps.health.pa.gov/ddc/> or contact the program at 717-787-4779 for more information. All interested parties are strongly encouraged to review applicable federal and state laws/regulations or seek legal counsel when appropriate.

COMPOUNDING REGULATIONS FINALIZED

The Pennsylvania State Board of Pharmacy's Compounding Regulations were published as final in *The Pennsylvania Bulletin* on June 22, 2019. The new regulations are provided here.

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 27. STATE BOARD OF PHARMACY

GENERAL PROVISIONS

§ 27.1. Definitions.

The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

* * * * *

Drug order—

(i) An oral or written order issued by a medical practitioner which is either written on or entered by computer into the medical record of a patient in an institution for the dispensing of a drug or device for administration to the patient.

(ii) The term does not include an order for a drug for a patient in an institution which the patient will self-administer which will be considered a prescription.

*FDA—*The United States Food and Drug Administration, a division of the United States Department of Health and Human Services.

*FDLE—*Federal Drug Law Examination.

* * * * *

Satellite pharmacy—

(i) A pharmacy in an institution which provides specialized services for the patients of the institution and which is dependent upon the centrally located pharmacy for administrative control, staffing and drug procurement.

(ii) The term does not include a pharmacy serving the public on the premises of an institution nor does it include a pharmacy located off premises from the centrally located pharmacy of the institution regardless of whether the pharmacy is owned by the same person or entity which owns the institution.

*USP—The United States Pharmacopeia—*A compendium of drug information published by the United States Pharmacopeial Convention.

STANDARDS

§ 27.12. Practice of pharmacy and delegation of duties.

* * * * *

(d) *Pharmacy technicians.*

(1) A pharmacy technician may work only under the direct, immediate, personal supervision of a pharmacist in accordance with subsection (b)(2).

(2) The following are examples of the types of activities which a pharmacy technician may perform:

* * * * *

(vi) Enter prescription, drug order or patient information in a patient profile.

(vii) Assist the pharmacist in the compounding of drug products, as permitted by the written protocol created and maintained in accordance with paragraph (4).

(3) A pharmacy technician may not:

* * * * *

COMPOUNDING

§ 27.601. Compounding of preparations.

The compounding of sterile and nonsterile preparations shall be done in accordance with section 503a of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. § 353a), Federal regulations promulgated thereunder, and the current version of the USP chapters governing compounding.

§ 27.602. Compounding prohibited.

Pharmacists may not compound any of the following:

(1) Drugs that have been identified by the FDA as withdrawn or removed from the market because the drugs were found to be unsafe or ineffective as set forth in 21 CFR 216.24 (relating to drug products withdrawn or removed from the market for reasons of safety or effectiveness) unless the drug is being used as part of a clinical trial and is approved by an institution's institutional review board.

(2) Drugs that are essentially copies of a commercially available drug product, except as provided in section 503a(b)(1)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. § 353a(b)(1)(D)).

(3) Drugs that have been identified by the FDA in the Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. §§ 301—399h) or the *Code of Federal Regulations* as products which may not be compounded.

§ 27.603. Pharmacist responsibilities.

(a) As in the dispensing of all prescription drugs, the pharmacist has the responsibility for all of the following:

(1) Inspection and approval or rejection of all components, bulk drug substances (that is, active pharmaceutical ingredients), drug product containers, closures, in-process materials and labeling.

(2) Preparation and review of all compounding records to assure that errors have not occurred in the compounding process.

(3) Proper maintenance, cleanliness and use of all facilities and equipment used in compounding practice.

(b) If errors have occurred, the pharmacist is responsible for conducting a full investigation, and creating and maintaining a record of the investigation which must include conclusions and corrective action.

§ 27.604. Drug compounding controls.

Accountability for quality control is the responsibility of the compounding pharmacist.

§ 27.605. Label information required.

The label affixed to or on the dispensing container of a compounded drug product dispensed by a pharmacy pursuant to a prescription or drug order must bear the information as required in § 27.18(d) (relating to standards of practice) and any additional information required by USP provisions pertaining to label information requirements.

§ 27.606. Compounding records.

Compounding records required by this chapter shall be retained as the original records and shall be readily available at the pharmacy for inspection and photocopying by agents of the Board or other authorized authorities for at least 2 years following the date of the record. Prescriptions for all products compounded at the pharmacy shall be

maintained on file at the pharmacy as required under § 27.18(b) (relating to standards of practice).

[Pa.B. Doc. No. 19-928. Filed for public inspection June 21, 2019, 9:00 a.m.]

No part of the information on this site may be reproduced for profit or sold for profit.

This material has been drawn directly from the official *Pennsylvania Bulletin* full text database. Due to the limitations of HTML or differences in display capabilities of different browsers, this version may differ slightly from the official printed versio