RULES AND REGULATIONS

Title 49—PROFESSIONAL AND VOCATIONAL STANDARDS

STATE BOARD OF PHARMACY

[49 PA. CODE CH. 27]

Compounding

The State Board of Pharmacy (Board) amends §§ 27.1 and 27.12 (relating to definitions; and practice of pharmacy and delegation of duties) and adds §§ 27.601—27.606 to read as set forth in Annex A.

Statutory Authority

This final-form rulemaking is authorized under sections 4(j) and 6(k)(1) and (9) of the Pharmacy Act (act) (63 P.S. §§ 390-4(j) and 390-6(k)(1) and (9)).

Background

Since at least 2010, the Board has been considering promulgating regulations setting standards for the compounding of drug products by pharmacists. Then, in October 2012, National headlines reported a meningitis outbreak of epidemic proportions. The cause was quickly identified as contaminated compounded injectable medications made by a commercial compounding pharmacy located in Massachusetts. Since that time, representatives of the Board have met with interested parties and stakeholders, including representatives from the United States Food and Drug Administration (FDA), with a goal of promulgating regulations incorporating developments and improvements in the profession's safe, sterile practices and procedures for the compounding of pharmaceutical products for patients.

To that end, the Board published a notice of proposed rulemaking at 47 Pa.B. 1509 (March 11, 2017). Publication of the proposal was followed by a 30-day public comment period. The Board received comments from the Pennsylvania Academy of Opthalmology; the Pennsylvania Allergy and Asthma Association; the American Academy of Dermatology and Pennsylvania Academy of Dermatology and Dermatologic Surgery; Cardinal Health; the Pennsylvania Medical Society; Patricia Clancy Keinle, RPh; the Pennsylvania Academy of Otolaryngology—Head and Neck Surgery (PAO-HNS); Christine Roussel, PharmD, Assistant Director of Pharmacy at Doylestown Health; the Pennsylvania Society of Health System Pharmacists; and the Pennsylvania Society of Oncology and Hematology and the American Society of Clinical Oncology. The Board also received comments from the House Professional Licensure Committee (HPLC) by letter dated April 25, 2017. The Pennsylvania Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) did not submit comments. On May 10, 2017, the Independent Regulatory Review Committee (IRRC) submitted their comments on the proposed rulemaking. IRRC's comments included fair summarizations of the comments received from the other commenters. The Board discussed the comments at several public meetings and voted to proceed with this final-form rulemaking at its meeting on January 7, 2019.

Summary of Comments, the Board's Response and Descriptions of Amendments

Generally

Initially, IRRC commented that the Preamble states that "all compounding shall be done in accordance with the current version of the *United States Pharmacopeia* (USP)," but pointed out that section 390-8(2) of the act (63 P.S. § 390-8(2)) provides that "nothing herein shall be construed to prevent a duly licensed medical practitioner from dispensing, compounding or otherwise giving any drug to his own patients after diagnosis or treatment of said patient, if such compounding, preparing and dispensing is done by said licensee himself. . . ." The comment included a request to clarify the effect, if any, of this regulation on licensed medical practitioners other than pharmacists. Commenters Pennsylvania Academy of Opthalmology, Pennsylvania Allergy and Asthma Association, American Academy of Dermatology and Pennsylvania Academy of Dermatology and Dermatologic Surgery, Pennsylvania Medical Society and the PAO-HNS expressed similar concerns.

The Board considered this comment and notes that nothing in the proposed regulation indicates it applies to practitioners other than pharmacists. The act does not provide the Board the authority to regulate practitioners other than pharmacists, and the Board feels the focus of the proposed regulation makes clear the Board's intent to regulate compounding by pharmacists only.

In the same comment, IRRC noted the questions on the inspection form attached to the regulatory analysis form apply only to sterile compounding and questioned whether there will be any changes to the inspection forms related to nonsterile compounding. The Board has revised the inspection form to include questions related to nonsterile compounding.

IRRC also pointed out the Board's inconsistent application of, or reference to, the USP chapters on compounding. Commenters, including Patricia Clancy Keinle, RPh and the Pennsylvania Society of Health System Pharmacists, likewise, ask the Board to remove sections that paraphrase existing USP chapters and to remove sections which appear in USP chapters in greater detail. Instead, commenters ask the Board to directly reference relevant USP chapters to avoid conflicting requirements in the future.

The Board considered these comments and the confusion that has apparently resulted from the Board's inconsistent treatment of the USP throughout the proposed rulemaking and decided to simplify the final-form rulemaking. In response to these comments, the Board has removed the sections which reference, paraphrase or which contain language that is otherwise covered by relevant USP provisions (§§ 27.603—27.605, 27.608—27.615, 27.617—27.619 and 27.622—27.624), and has renumbered the remaining six sections. Instead, the Board will rely on § 27.601 (relating to compounding of preparations), as amended in this final-form rulemaking, to require compounding pharmacists to adhere to section 503a of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. § 353a), the Federal regulations promulgated thereunder, and the current version of the USP chapters governing compounding. These amendments ensure the regulations do not conflict with FDA requirements going forward.

§ 27.1 (relating to definitions)

Cardinal Health suggested that the definition of compounding should be modified to clarify that compounding does not include reconstitution of a drug product under a manufacturer's direction. Similarly, the Pennsylvania Society of Hematology and Oncology and the American Society of Clinical Oncology requested clarification that the proposed compounding regulations do not apply to the routine dilution and reconstitution of drug products. Section 503a(e) of the Federal Food, Drug, and Cosmetic Act provides "the term 'compounding' does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling." The Board considered this suggestion and determined the Federal definition is an industry-wide standard and so well-known to the regulated community of pharmacists that it is unnecessary to duplicate it within this final-form rulemaking.

§ 27.12 (relating to practice of pharmacy and delegation of duties)

IRRC and the HPLC raised a concern related to § 27.12(d)(2)(vii) and requested additional information to clarify what pharmacy technicians may do and what they are prohibited from doing when assisting in the compounding of drug products. In response, the Board notes the delegation provisions already in place in § 27.12(b)(2), which require the pharmacist to provide direct, immediate and personal supervision of pharmacy technicians. Direct, immediate and personal supervision means the supervising pharmacist must review the prescription or drug order, verify the final product and be immediately available on the premises to direct the work of the pharmacy technicians and to respond to questions or problems. Further, § 27.12(d)(3) provides that pharmacy technicians may not enter or be in a pharmacy if a pharmacist is not on duty, perform any act within the practice of pharmacy that involves discretion or independent judgment, or perform a duty until the technician has been trained and the duty has been specified in a written protocol. Finally, § 27.12(d)(4) provides that the pharmacist manager shall create and maintain a written protocol for each pharmacy technician, specifying each duty the pharmacy technician may perform.

The proposed regulation sought to add a new subparagraph (vii) under § 27.12(d)(2) which states specifically that a pharmacy technician may assist in the compounding of drug products. To provide some clarity and direction, the Board has added to subparagraph (vii) in this final-form rulemaking "as permitted by the written protocol created and maintained in accordance with paragraph (4)."

§ 27.602 (relating to compounding commercially available product)

The American Academy of Dermatology and the Pennsylvania Academy of Dermatology and Dermatologic Surgery noted that this section incorporates the FDA's draft guidance on compounding drugs that are essentially copies of commercially available drug products, with the addition of proposed language permitting such compounding if it is "in the best interest of the patient." They ask if the FDA were to adopt its draft guidance, would the FDA's guidance supersede Commonwealth law? In addition, Cardinal Health commented that a pharmacist using a commercially manufactured, FDA approved drug product in the course of compounding will not have COAs (certificates of analysis) for these FDA-approved drugs, and asked that the Board consider this scenario.

In response, and to eliminate any confusion regarding § 27.602 and FDA requirements and definitions, the Board has removed this section from this final-form rulemaking and will rely on the reference to the Federal requirements and the USP in § 27.601.

§ 27.603 (relating to bulk drug substances)

IRRC raised a concern that the Board proposes to adopt the FDA Pharmacy Compounding of Human Drug Products Under Section 503a of the Federal Food, Drug, and Cosmetic Act Guidance (FDA Guidance) concerning bulk drug substances, but the proposed regulation provides for an exception for bulk drug substances that are not subject to a monograph in paragraph 2(iii) to allow for bulk drug substances that "peer-reviewed literature supports and, in the professional judgment of the pharmacist and prescriber, demonstrates the safety and effectiveness of the bulk drug substances." IRRC notes a concern that this exception is not regulatory language, does not set a binding norm, and the FDA Guidance does not allow for it. The American Academy of Dermatology and Pennsylvania Academy of Dermatology and Dermatologic Surgery raise a similar concern.

To address these concerns, the Board has removed this section from this final-form rulemaking and will rely on the reference to the Federal requirements and the USP in § 27.601, which simply requires compounding pharmacists to adhere to section 503a of the Federal Food, Drug, and Cosmetic Act, the Federal regulations promulgated thereunder and the relevant USP chapters on compounding.

Commenters Patricia Clancy Keinle, RPh, and Christine Roussel, PharmD, indicated concerns with the use of the term "bulk drug substance," noting its possible confusion with the term "active pharmaceutical ingredients," which is the common term used in the USP. Although this section has been removed from this final-form rulemaking, the Board notes that "bulk drug substance" is the term used in section 503a of the Federal Food, Drug, and Cosmetic Act, and that regulations at 21 CFR 207.3 (relating to bulk drug substance) provide that "[b]ulk drug substance, as referenced in sections 503a(b)(1)(A) and 503b(a)(2) of the Federal Food, Drug, and Cosmetic Act, previously defined in § 207.3(a)(4), means the same as 'active pharmaceutical ingredient' as defined in § 207.1(b)." Thus, the terms are interchangeable.

§§ 27.604 and 27.605 (relating to dispensing compounded drugs; and resale of compounded drug products)

IRRC expressed a concern that § 27.604 identifies a "specific patient" while § 27.605 uses "individual patient," and asked the Board to ensure this final-form rulemaking is consistent and clear. The Pennsylvania Academy of Opthalmology also asked if the use of different terms in these two sections means that specific patients do not need to be identified for each compounded drug that is delivered by means of wholesale distribution to a medical practitioner.

IRRC also asked whether the provisions in §§ 27.604 and 27.605 prohibit dispensing compounded drugs "for office use." Both IRRC and the Pennsylvania Medical Society asked whether these provisions (1) prohibit dispensing compounded drugs "for office use," (2) limit a physician's ability to order and purchase compounded drugs from the compounding pharmacy for the purposes of storing them in the office for future use, or (3) require a patient-specific prescription in order for a pharmacy to

be able to send a batch of a compounded drug directly to a physician for administration to a patient.

To eliminate this confusion, the Board has removed these sections from this final-form rulemaking. Instead, the Board will rely on the reference to the Federal requirements and the USP in § 27.601. However, the Board would point out that section 503a of the Federal Food, Drug, and Cosmetic Act uses the terms "identified individual patient" and "identified patient."

Finally, Patricia Clancy Keinle, RPh, Christine Roussel, PharmD and the Pennsylvania Society of Health System Pharmacists suggested that the Board clarify that distribution of a compounded drug product within a health-system is not considered resale. Although the Board has now removed this section, the Board notes that neither the act nor the Board's regulations, current or proposed, address distribution of a compounded drug product within a health-system.

§ 27.606 (relating to compounding prohibited)

IRRC mentioned the concern raised by Christine Roussel, PharmD and the Pennsylvania Society of Health System Pharmacists that subsection (1) may conflict with a clinical trial where a drug that has been removed from the market is now being used for investigational purposes after approval from an institution's Institutional Review Board. Upon consideration of this concern, and after discussion with stakeholders, the Board decided to add to paragraph (1) the proviso "unless the drug is being used as part of a clinical trial and is approved by an institution's Institutional Review Board." Additionally, because the Board has now deleted proposed § 27.602, the Board replaced the reference to § 27.602 in paragraph (2) with a reference to the relevant provision in the Federal Food, Drug, and Cosmetic Act. Finally, this section has been renumbered as § 27.602 in this final-form rulemaking.

§ 27.607 (relating to pharmacist responsibilities)

Commenters Patricia Clancy Keinle, RPh and Christine Roussel, PharmD indicated concerns with the use of the term "bulk drug substance," noting its possible confusion with the term "active pharmaceutical ingredient," which is the common term used in the USP. As noted previously, "bulk drug substance" is the term used in section 503a of the Federal Food, Drug, and Cosmetic Act, and that regulations at 21 CFR 207.3 provide that "[b]ulk drug substance, as referenced in sections 503a(b)(1)(A) and 503b(a)(2) of the Federal Food, Drug, and Cosmetic Act, previously defined in § 207.3(a)(4), means the same as 'active pharmaceutical ingredient' as defined in § 207.1(b)." Thus, the terms are interchangeable.

To eliminate the noted confusion, and in light of the use of the term "active pharmaceutical ingredients" in the USP and as commonly used within the industry, the Board deemed it advisable to include a reference to active pharmaceutical ingredients in paragraph (a)(1). Finally, this section has been renumbered as § 27.603 in this final-form rulemaking.

§ 27.608 (relating to protective apparel)

IRRC noted that this section states that sterile gowning components are necessary "as required by the USP chapter on sterile compounding" and that a comment by Cardinal Health raised concerns that not all gowning components required by USP Chapter 797 are sterile. The Board notes that there are different protective apparel requirements under USP Chapter 795 (nonsterile), Chapter 797 (sterile) and Chapter 800 (hazardous drugs). In response, the Board has removed this section from this final-form rulemaking and instead will rely on the general reference to the Federal requirements and the USP in § 27.601. The result is that pharmacists are required to follow the applicable protective apparel requirements of Chapters 795, 797 and 800 of the USP.

§ 27.609 (relating to drug compounding facility requirements)

Drug compounding facility requirements are adequately addressed in the current version of the USP chapters on compounding. Therefore, to remain consistent with other revisions, the Board removed this section and will rely on the reference to the Federal requirements and the USP in § 27.601.

§ 27.610 (relating to equipment)

This section merely referred to compliance with USP chapters on equipment, and to remain consistent with other revisions, the Board removed this section and will rely on the general reference to the Federal requirements and the USP in § 27.601.

§ 27.611 (relating to equipment maintenance)

This section merely referred to compliance with USP chapters on equipment maintenance, and to remain consistent with other revisions, the Board removed this section and will rely on the reference to the Federal requirements and the USP in § 27.601.

§ 27.612 (relating to specialized equipment)

Specialized equipment for compounding is adequately addressed in the current version of the USP chapters on compounding. Therefore, to remain consistent with other revisions, the Board removed this section and will rely on the reference to the Federal requirements and the USP in § 27.601.

§ 27.613 (relating to use of automated equipment)

Use of automated equipment for compounding is adequately addressed in the current version of the USP chapters on compounding. Therefore, to remain consistent with other revisions, the Board removed this section and will rely on the reference to the Federal requirements and the USP in § 27.601.

§ 27.614 (relating to control of containers and closures)

This section merely referred to compliance with USP chapters on control of containers and closures, and to remain consistent with other revisions, the Board removed this section from this final-form rulemaking and will rely on the reference to the Federal requirements and the USP in § 27.601.

§ 27.615 (relating to storage)

This section generally referred to compliance with USP chapters on storage but added specific requirements which are adequately addressed in USP storage requirements. To eliminate potential confusion between the addition of specific requirements and wording in the USP chapters, and to remain consistent with other revisions, the Board removed this section and will rely on the reference to the Federal requirements and the USP in § 27.601.

§ 27.616 (relating to drug compounding controls)

This section has been renumbered as § 27.604 in this final-form rulemaking.

§ 27.617 (relating to standard operating procedures required)

Commenter Patricia Clancy Kienle, RPh recommended deleting the second and third sentence of subsection (a)

because this information is already detailed in the USP. Patricia Clancy Kienle, RPh and Christine Roussel, PharmD recommended deleting the phrase "including validation of any sterilization process" from subsection (b) because it is described in USP Chapter 797, and that USP Chapter 797 does not require every sterile preparation to be tested.

IRRC and Patricia Clancy Keinle, RPh highlighted the contradiction in subsection (c) where it states control procedures must include all of the following as appropriate. Further, IRRC also pointed out that "as appropriate" is vague and does not set a measurable standard. Patricia Clancy Keinle, RPh recommended removing the last sentence and the numbered bullets because "this is detailed in USP chapters." Additionally, Cardinal Health commented that a pharmacist solely using a commercially manufactured, FDA approved drug product in the course of compounding should not need to perform pH testing of solutions. In response, the Board has decided to remove the entire section, and will rely on the reference to the Federal requirements and the USP in § 27.601, which as the commenters aptly point out are sufficiently detailed.

§ 27.618 (relating to accuracy)

Accuracy regarding weights and measurements, and container requirements are adequately addressed in the current version of the USP chapters on compounding. Therefore, to remain consistent with other revisions, the Board removed this section and will rely on the reference to the Federal requirements and the USP in § 27.601.

§ 27.619 (relating to production record)

Production record requirements are adequately addressed in the USP chapters on compounding. Therefore, to remain consistent with other revisions, the Board removed this section and will rely on the reference to the Federal requirements and the USP in § 27.601.

§ 27.620 (relating to label information required)

The HPLC asked whether the label information required in this section would include all of the information currently found on the label of a noncompounded prescription medication. The Board believes the reference to § 27.18(d) (relating to standards of practice) clarifies, with certainty, that compounded medication containers must comply with the labeling requirements set forth in § 27.18(d), which apply to all prescription drug containers.

IRRC noted that this section requires compliance with § 27.18(d), which, among other things, requires the DEA number of the pharmacy to be included on the container. Noting the comment by Cardinal Health, that not all pharmacies possess a DEA registration and do not possess nor dispense controlled substances, IRRC asked the Board to consider this scenario and to ensure that this final-form rulemaking is reasonable and clear for the regulated community. The Board considered this comment and believes the reference to § 27.18(d) is appropriate, and the Board notes that the possibility that a pharmacy might not have a DEA registration number is being addressed by the Board in a separate upcoming "general revisions" rulemaking package.

Commenters Patricia Clancy Kienle, RPh and the Pennsylvania Society of Health System Pharmacists mention that the USP provides more detail regarding required label information. The Board decided to remove paragraphs (1) and (2) to avoid confusion and potential conflict if the USP changes its standards in the future. In its place, the Board added the phrase "any additional information required by USP provisions related to label information requirements."

In addition, this section has been renumbered as § 27.605 in this final-form rulemaking.

§ 27.621 (relating to compounding records)

Commenters Patricia Clancy Kienle, RPh and the Pennsylvania Society of Health System Pharmacists recommend removing this section, but moving the 2-year record retention requirement to another section. The Board considered this comment, but decided to make no changes, other than renumbering this section as § 27.606 in this final-form rulemaking. The Board believes this section provides context to the record retention requirement and is not inconsistent with the USP. Further, the Board believes that, because of its reference to § 27.18(b), it is consistent with other pharmacy recordkeeping requirements.

§§ 27.622 and 27.623 (relating to master formula record; and production record for drugs compounded in bulk quantities)

IRRC and commenters Patricia Clancy Kienle, RPh and Christine Roussel, PharmD note the Board's use of "formula record" in § 27.622 and "production record" in § 27.623 is confusing and inconsistent with the USP. The commenters note that the USP defines two types of records: Master Formulation Record and Compounding Record. The Board agrees with these comments, and to remain consistent with other revisions, the Board removed this section and will rely on the general reference to the Federal requirements and the USP in § 27.601.

§ 27.624 (relating to label information)

This section applied to labels affixed to each container of batch drug products compounded, rather than labels for containers which are dispensed to the ultimate user as described in § 27.620. The USP chapters on compounding adequately address information requirements on labels for batch drug products. Therefore, to remain consistent with other revisions, the Board removed this section and will rely on the reference to the Federal requirements and the USP in § 27.601.

Miscellaneous

IRRC's final comment addresses the use of the term "bulk" throughout the proposal and asked the Board to either define the term or clarify the applicability of the term within the section in which it is used. In response to this comment and similar concerns raised by Patricia Clancy Keinle, RPh, Christine Roussel, PharmD and the Pennsylvania Society of Health-System Pharmacists, the Board has eliminated potential inconsistencies by removing proposed §§ 27.603, 27.604, 27.619, 27.622 and 27.623 from this final-form rulemaking.

Fiscal Impact

This final-form rulemaking would have little fiscal impact on the Commonwealth, its political subdivisions or the public. Any pharmacy that elects to engage in compounding pharmaceuticals may incur a cost relating to compliance with the standards set forth in this final-form rulemaking. However, as the Board is unable to determine at this time how many pharmacies engage in compounding or may elect to do so at some future date, it is impossible to estimate the fiscal impact on the regulated community. As FDA and USP requirements are already in place, and the regulation provides no additional substantive requirements or prohibitions, it is

likely that there will be little, if any, costs to pharmacies for compliance with this final-form rulemaking.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a), on March 1, 2017, the Board submitted a copy of the notice of proposed rulemaking, published at 47 Pa.B. 1509, to IRRC and the chairpersons of the HPLC and the SCP/PLC for review and comment.

Under section 5(c) of the Regulatory Review Act, IRRC, the HPLC and the SCP/PLC were provided with copies of the comments received during the public comment period, as well as other documents when requested. In preparing this final-form rulemaking, the Board has considered all comments from IRRC, the HPLC and the public. The Board received no comments from the SCP/PLC.

On April 9, 2019, the Board delivered this final-form rulemaking to IRRC, the HPLC and the SCP/PLC. Under section 5.1(j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2)), on May 15, 2019, this final-form rulemaking was deemed approved by the HPLC and the SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on May 16, 2019, and approved this final-form rulemaking.

Additional Information

Individuals who need information about this final-form rulemaking may contact Melanie Zimmerman, RPh, Executive Secretary, State Board of Pharmacy, P.O. Box 2649, Harrisburg, PA 17105-2649, st-pharmacy@pa.gov.

Findings

The Board finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201 and 1202) and the regulations promulgated thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law and all comments were considered.

(3) The amendments to this final-form rulemaking do not enlarge the original purpose of the proposed rulemaking published at 47 Pa.B. 1509.

(4) This final-form rulemaking is necessary and appropriate for the administration of the act.

Order

The Board, acting under its authorizing statute, orders that:

(a) The regulations of the Board at 49 Pa. Code Chapter 27 are amended by amending §§ 27.1 and 27.12 and by adding §§ 27.601—27.606 to read as set forth in Annex A.

(b) The Board shall submit this Order and Annex A to the Office of Attorney General and the Office of General Counsel for approval as required by law.

(c) The Board shall submit this order and Annex A to IRRC, the HPLC and the SCP/PLC as required by law.

(d) The Board shall certify this Order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(e) This final-form rulemaking shall take effect upon publication in the *Pennsylvania Bulletin*.

THERESA M. TALBOTT, RPh,
Chairperson

(*Editor's Note*: See 49 Pa.B. 2799 (June 1, 2019) for IRRC's approval order.)

Fiscal Note: 16A-5419. No fiscal impact; additional inspection costs would be absorbed by the Board and licensing fees would be adjusted accordingly; (8) recommends adoption.

Annex A

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.]

Title 58—RECREATION

FISH AND BOAT COMMISSION

[58 PA. CODE CH. 65]

Fishing; Special Fishing Regulations

The Fish and Boat Commission (Commission) amends Chapter 65 (relating to special fishing regulations). The Commission is publishing this final-form rulemaking under the authority of 30 Pa.C.S. (relating to Fish and Boat Code) (code). The amendments update the Commission's list of waters subject to special regulations.

A. *Effective Date*

This final-form rulemaking will go into effect upon publication in the *Pennsylvania Bulletin*.

B. *Contact Person*

For further information on this final-form rulemaking, contact Wayne Melnick, Esq., P.O. Box 67000, Harrisburg, PA 17106-7000, (717) 705-7810. This final-form rulemaking is available on the Commission's web site at www.fish.state.pa.us.

C. *Statutory Authority*

The amendments to § 65.24 (relating to miscellaneous special regulations) are published under the statutory authority of section 2307 of the code (relating to waters limited to specific purposes).

D. *Purpose and Background*

The specific purpose and background of the amendments is described in more detail under the summary of changes.

E. *Summary of Changes*

Chapman Dam Reservoir, a 67.95-acre impoundment owned by the Department of Conservation and Natural Resources, is located within Chapman State Park, Pleasant Township, Warren County, approximately 6 miles south of the City of Warren. This reservoir was completely dewatered during fall 2017 to remove sediment and to complete control tower, dam and spillway repairs and modifications per Department of Environmental Protection dam safety standards. The earth-fill dam, constructed in 1949, impounds the West Branch Tionesta Creek at river-mile 14.7 upstream from its confluence with Tionesta Creek at river-mile 40.3. Prior to the drawdown in 2017, the lake offered angling opportunities for multiple warm-water and cool-water fish species, as well as adult trout stocked by the Commission. Sediment removal and dam and spillway repairs are expected to be completed by early 2019 with refilling initiated soon after.

The Commission plans to initiate stocking the lake beginning in spring 2019 or as soon as refilling conditions allow with fingerling plants of select fish species to establish a high quality warm-water and cool-water fishery. Immediately upon refilling of the lake, staff propose to open the lake to fishing under a miscellaneous special regulation that will allow for the harvest of trout under Commonwealth Inland Waters angling regulations but allow only catch and release fishing for all other fish species. Staff believe that this approach will allow for the most rapid development of a balanced warm-water and cool-water fish community, while offering acceptable levels of recreational angling opportunities. Fisheries Management staff will monitor the fish populations as needed while they develop and make necessary modifications to the species stocked and recommend adjustments to the regulations governing fish harvest to the Board of Commissioners to continually provide high quality recreational angling opportunities at Chapman Dam Reservoir. Once the warm-water fishery has been reestablished, the lake will be recommended for removal from the miscellaneous special regulation and inclusion in one of the Commission's existing warm-water regulation programs.

The Commission therefore amends § 65.24 to read as set forth in the proposed rulemaking published at 48 Pa.B. 7643 (December 15, 2018).

F. *Paperwork*

This final-form rulemaking will not increase paperwork and will not create new paperwork requirements.

G. *Fiscal Impact*

This final-form rulemaking will have no adverse fiscal impact on the Commonwealth or its political subdivisions.

H. *Public Involvement*

A notice of proposed rulemaking was published at 48 Pa.B. 7643. The Commission received no public comment.

Findings

The Commission finds that:

(1) Public notice of intention to adopt the amendments adopted by this order has been given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§ 1201 and 1202) and the regulations promulgated thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided, and no public comments were received.

(3) The adoption of the amendments of the Commission in the manner provided in this order is necessary and appropriate for administration and enforcement of the authorizing statutes.

Order

The Commission, acting under the authorizing statutes, orders that:

(A) The regulations of the Commission, 58 Pa. Code Chapter 65, are amended by amending § 65.24 to read as set forth at 48 Pa.B. 7643.

(B) The Executive Director will submit this order and 48 Pa.B. 7643 to the Office of Attorney General for approval as to legality and form as required by law.

(C) The Executive Director shall certify this order and 48 Pa.B. 7643 and deposit them with the Legislative Reference Bureau as required by law.

(D) This order shall take effect upon publication in the *Pennsylvania Bulletin*.

TIMOTHY D. SCHAEFFER,
Executive Director

Fiscal Note: Fiscal Note 48A-288 remains valid for the final adoption of the subject regulation.

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