

# Regulatory Analysis Form

(Completed by Promulgating Agency)

**INDEPENDENT REGULATORY  
REVIEW COMMISSION**

(All Comments submitted on this regulation will appear on IRRC's website)

(1) Agency  
**Department of State, Bureau of Professional and Occupational  
 Affairs, State Board of Pharmacy**

(2) Agency Number: **16A**  
 Identification Number: **5419**

IRRC Number:

**3163**

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IRRC  
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(3) PA Code Cite: **49 Pa. Code §§ 27.1, 27.12, 27.601—27.264**

(4) Short Title: **Compounding**

(5) Agency Contacts (List Telephone Number and Email Address):

Primary Contact: **Kerry Maloney, Board Counsel, State Board of Pharmacy; (717)783-7200;  
 kmaloney@pa.gov**

Secondary Contact: **Cynthia K. Montgomery, Regulatory Counsel, Department of State; (717) 783-  
 7200; cymontgome@pa.gov**

(6) Type of Rulemaking (check applicable box):

**PROPOSED REGULATION**

Final Regulation

Final Omitted Regulation

Emergency Certification Regulation;

Certification by the Governor

Certification by the Attorney General

(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)

**The rulemaking amends existing regulations at §§ 27.1 and 27.12 (relating to definitions; and practice of pharmacy and delegation of duties), and adds §§ 27.601—27.624 (relating to compounding). The main objectives of the rulemaking are: (1) to update the Board's regulations to incorporate developments and improvements in the profession's safe, sterile practices and procedures for the compounding of pharmaceutical products for patients; (2) to allow pharmacy technicians to assist the pharmacist in the compounding of pharmaceutical products; and (3) to aid enforcement by setting forth standards for the compounding of pharmaceutical products.**

(8) State the statutory authority for the regulation. Include specific statutory citation.

**This 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)).**

(9) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

**The regulation is not mandated by any federal or state law or court order, or federal regulation. It is consistent with, and refers to when appropriate, regulations of the FDA relating to pharmacy compounding and incorporates the relevant sections of the current version of the United States Pharmacopoeia (USP) as set forth under section 503a of the Federal Food, Drug and Cosmetic Act (21 U.S.C.A. § 353a) and the FDA's Guidance document relating to "Pharmacy Compounding of Human Drug Products Under Section 503a of the Federal Food, Drug and Cosmetic Act," a copy of which is attached hereto and is available for review on the FDA's website at the following link: <http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm469119.pdf>.**

(10) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

**In October 2012, national headlines reported a meningitis outbreak of epidemic proportions. The cause was quickly identified as contaminated compounded injectable medication made by a commercial compounding pharmacy located in Massachusetts.**

**The regulation is needed to update the Board's current regulations to incorporate developments and improvements in the profession's safe, sterile practices and procedures for the compounding of pharmaceutical products for patients. The public will benefit because currently the Board does not have specific regulations that address safe compounding practices. Enforcement of these minimum standards will benefit the citizens of the Commonwealth who are consumers of compounded drug products.**

(11) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulations.

**The Rulemaking is not more stringent and does not conflict with any federal requirements. In fact, it conforms to the FDA's requirements for pharmacy compounding of human drug products under section 503a of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. § 353a).**

(12) How does this regulation compare with those of the other states? How will this affect Pennsylvania's ability to compete with other states?

**All surrounding states regulate the preparation of compounded drug products. New York regulates the practice of compounding in accordance with United States Pharmacopeia (USP) Chapter 797. (Article 137 §6831). Likewise, Maryland requires permits for sterile compounding pursuant to COMAR 10.34.19 and 10.34.09. West Virginia requires permits pursuant to W. Va. Code § 15-1-16. New Jersey regulates sterile and non-sterile compounding in accordance with USP Chapters 797 and 795. (N.J.A.C. 13:39-11.1 and 13:39-11A.1) Likewise, Ohio also regulates sterile and non-sterile compounding in accordance with USP Chapters 797 and 795 pursuant to Ohio Admin. Code Rule 4729-9-21. Finally, Delaware regulates sterile compounding pursuant to section 10.0 of Title 24 Regulated Professions and Occupations of the Delaware Administrative Code. All of the surrounding states incorporate similar versions of USP Chapters 797 and 795 regarding sterile and non-sterile drug compounding. Therefore, these regulations should not put Pennsylvania at a competitive disadvantage with the surrounding states.**

(13) Will the regulation affect any other regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

**The rulemaking does not affect other regulations of the Board or other state agencies.**

(14) Describe the communications with and solicitation of input from the public, any advisory council/group, small businesses and groups representing small businesses in the development and drafting of the regulation. List the specific persons and/or groups who were involved. ("Small business" is defined in Section 3 of the Regulatory Review Act, Act 76 of 2012.)

**In accordance with Executive Order 1996-1, the Board sent an exposure draft of this proposed rulemaking to pharmacy and professional associations, hospitals, pharmacy schools and other stakeholders that the Board has identified as having an interest in this rulemaking and received input from interested parties in 2007. After the 2012 meningitis outbreak, the Board revamped the original draft and sent out a new exposure draft. The Board discussed the proposed rulemaking at numerous public meetings including a meeting with stakeholders: Steven L. Sheaffer, Pharm.D., Philadelphia College of Pharmacy, Nishaminy Kasbekar, Pharm.D., Director of Pharmacy, PENN Presbyterian Medical Center, Bob Begliomini, Pharm.D., Administrator Lehigh Valley Health Network, Patricia C. Kienle, R.Ph., Cardinal Health, Mark Pimley, R.Ph., Patricia Epple, CEO Pennsylvania Pharmacists Association, and Richard Demers, R.Ph., Director of Pharmacy, University of Penn Hospital, in January of 2013 and received comments from the Pennsylvania Medical Society in November of 2013. After meeting with its stakeholders, the Board voted to adopt the proposed rulemaking at its meeting held on June 10, 2014. In addition, public meetings of the Board are routinely attended by interested parties and stakeholders, including representatives from the Pennsylvania Pharmacists' Association.**

(15) Identify the types and number of persons, businesses, small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012) and organizations which will be affected by the regulation. How are they affected?

**All pharmacists who compound drugs will be impacted by the regulations. There are currently approximately 22,365 pharmacists and 3,429 pharmacies licensed by the Board. The Board does not currently maintain statistics on how many pharmacies engage in compounding.**

**According to the Pennsylvania Department of Labor and Industry, most pharmacists work in health and personal care stores (48.7%) and general medical and surgical hospitals (23.5%), while a minority of pharmacists work in grocery stores (6.9%), druggists' goods merchant wholesalers (2.4%), other hospitals (2.0%), the Federal government (1.7%), home health care services (0.7%), and 0.4% are self-employed.**

**According to the Small Business Administration (SBA), as of 2015, there are approximately 1,003,722 businesses in Pennsylvania, of which 999,591 are considered small businesses. Of the 999,591 small businesses, 225,382 are small employers (those with fewer than 500 employees) and the remaining 774,209 are small businesses without employees (non-employers). Thus, the vast majority of businesses in Pennsylvania are considered small businesses.**

**Small businesses are defined in Section 3 of the Regulatory Review Act, (71 P.S. § 745.3) which provides that a small business is defined by the SBA's Small Business Size Regulations under 13 CFR Ch. 1 Part 121. These size standards have been established for types of businesses under the North American Industry Classification System (NAICS). In applying the NAICS standards to the places where pharmacists work, a small business for pharmacies and drug stores is \$27.5 million or less in average annual receipts. For general medical and surgical hospitals, a small business is \$38.5 million or less in average annual receipts. Grocery stores consisting of supermarkets and other grocery stores (except convenience stores) have a small business threshold of \$32.5 million or less in average annual receipts. The small business threshold for home health care services is \$15.0 million or less in average annual receipts. For all other health and personal care stores, the small business threshold is \$7.5 million or less in average annual receipts. Finally, in terms of wholesalers, medical, dental and hospital equipment and supplies merchant wholesalers are considered small businesses if they have 200 or less employees.**

**In Pennsylvania, some of the 3,429 licensed pharmacies are small businesses owned and operated by individuals, however, many pharmacies would not qualify as "small businesses" under the SBA definition (large retail chains, for example). Whether or not pharmacists work in small or large businesses, this regulation will affect only those who engage in the practice of compounding. And the Board expects the effects to be positive for those businesses.**

(16) List the persons, groups or entities, including small businesses, that will be required to comply with the regulation. Approximate the number that will be required to comply.

**All pharmacies and pharmacists who elect to compound drugs would be required to comply with the provisions of this rulemaking. There are approximately 22,365 pharmacists and 3,429 pharmacies currently licensed by the Board. The Board has no way of knowing how many pharmacists/pharmacies will elect to engage in compounding.**

(17) Identify the financial, economic and social impact of the regulation on individuals, small businesses, businesses and labor communities and other public and private organizations. Evaluate the benefits expected as a result of the regulation.

**The Board currently has no regulations governing compounding practices and developments in the profession have led to the adoption of similar regulations by the surrounding states. The only costs to pharmacies associated with the regulation relate to maintaining the appropriate records along with the necessary equipment. Because the regulations are for the most part adopting the FDA industry standards, most pharmacies practicing compounding already have the required equipment. The benefits of articulated regulations setting forth good compounding practices will enhance the quality of service for patients as well as the safety of compounded drugs as a result of those practices and aid in enforcement.**

(18) Explain how the benefits of the regulation outweigh any cost and adverse effects.

**The benefits of ensuring the safe practice of compounding as set forth above greatly outweigh the costs of compliance and recordkeeping.**

(19) Provide a specific estimate of the costs and/or savings to the **regulated community** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

**Pharmacies that elect to participate in the compounding of sterile or non-sterile drug products might incur additional costs to ensure their pharmacy operation is in compliance with the current USP chapters regarding safety and equipment standards as required by the proposed regulations. It is believed that most Pennsylvania pharmacies would have already made any required changes based on these industry standards in protection of the public since the 2012 meningitis outbreak. Because the Board does not currently maintain statistics on how many of the 3,429 actively licensed pharmacies engage in compounding of pharmaceuticals, it is impossible to estimate the costs associated with compliance.**

(20) Provide a specific estimate of the costs and/or savings to the **local governments** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

**There are no costs or savings to local governments associated with the rulemaking.**

(21) Provide a specific estimate of the costs and/or savings to the **state government** associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.

**There may be minimal costs associated with a longer inspection process when pharmacies decide to engage in compounding sterile and non-sterile products. Currently, all pharmacies undergo initial opening inspections and also periodic random routine inspections. These inspections may take longer to complete to ensure compliance with the new regulations but they will not result in additional inspections. Any additional inspection costs would be assumed by the Board and borne by the licensees through their license fees. Because the Board has no way of knowing how many pharmacies will elect to participate in sterile or non-sterile compounding, any estimate of such costs would be speculative.**

(22) For each of the groups and entities identified in items (19)-(21) above, submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

**Pharmacies that engage in sterile and non-sterile compounding will have to ensure compliance with the regulations as drafted and keep appropriate records that will be the subject of facility inspections.**

(22a) Are forms required for implementation of the regulation?

**The Board will have to update its inspection forms to include enforcement of the compounding requirements.**

(22b) If forms are required for implementation of the regulation, **attach copies of the forms here.** If your agency uses electronic forms, provide links to each form or a detailed description of the information required to be reported. **Failure to attach forms, provide links, or provide a detailed description of the information to be reported will constitute a faulty delivery of the regulation.**

**A sample inspection form is attached. Because the inspections are conducted using a computer based system, the form will not be updated until the Board is closer in time to implementation as it will take significant staff time to program the new questions in to the system. However, attached is a list of draft questions that will be added to the inspection system for those pharmacies that engage in compounding.**

(23) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	<b>Current FY Year</b>	<b>FY +1 Year</b>	<b>FY +2 Year</b>	<b>FY +3 Year</b>	<b>FY +4 Year</b>	<b>FY +5 Year</b>
<b>SAVINGS:</b>	\$	\$	\$	\$	\$	\$
<b>Regulated Community</b>						
<b>Local Government</b>						
<b>State Government</b>						
<b>Total Savings</b>	N/A	N/A	N/A	N/A	N/A	N/A
<b>COSTS:</b>						
<b>Regulated Community</b>						
<b>Local Government</b>						
<b>State Government</b>						
<b>Total Costs</b>	N/A	N/A	N/A	N/A	N/A	N/A
<b>REVENUE LOSSES:</b>						
<b>Regulated Community</b>						
<b>Local Government</b>						
<b>State Government</b>						
<b>Total Revenue Losses</b>	N/A	N/A	N/A	N/A	N/A	N/A

(23a) Provide the past three year expenditure history for programs affected by the regulation.

<b>Program</b>	<b>FY 2013-14</b>	<b>FY 2014-15</b>	<b>FY 2015-16</b>	<b>Current FY (2016-17) (budgeted)</b>
<b>State Board of Pharmacy</b>	\$2,347,392	\$2,318,282	\$2,537,916	\$2,551,000 (budgeted)

(24) For any regulation that may have an adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), provide an economic impact statement that includes the following:

- (a) An identification and estimate of the number of small businesses subject to the regulation.
- (b) The projected reporting, recordkeeping and other administrative costs required for compliance with the proposed regulation, including the type of professional skills necessary for preparation of the report or record.
- (c) A statement of probable effect on impacted small businesses.
- (d) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation.

**As outlined above, the Board does not expect this regulation to have an adverse impact on small businesses. In fact, the benefits of this regulation as it pertains to public protection should vastly outweigh the costs involved. As most pharmacies practicing compounding already possess the equipment and facilities as set forth in these regulations based on the existing industry standards, any costs associated with the regulations are likely limited to the recordkeeping requirements.**

(25) List any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, the elderly, small businesses, and farmers.

**The Board has determined that there are no special needs of any subset of its licensees for whom special accommodations should be made.**

(26) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

**No alternative regulatory schemes were considered. The Board believes that the regulations represent the least burdensome acceptable manner of accomplishing the Board's mandate in protecting the public health, safety and welfare with regard to compounded pharmaceutical products.**

(27) In conducting a regulatory flexibility analysis, explain whether regulatory methods were considered that will minimize any adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), including:

- a) The establishment of less stringent compliance or reporting requirements for small businesses;
- b) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;
- c) The consolidation or simplification of compliance or reporting requirements for small businesses;
- d) The establishment of performance standards for small businesses to replace design or operational standards required in the regulation; and
- e) The exemption of small businesses from all or any part of the requirements contained in the regulation.

- a) **The compliance/reporting requirements required of any business, including small businesses, under this proposed regulation is based on the industry standard for compounding and as such, promotes public health and safety. The Board did not consider making any exceptions for small businesses. To do so would compromise the safety of the consumers of compounded drug products.**
- b) **The regulations establish no schedules or deadlines for which small businesses need to be accommodated.**
- c) **The Board does not believe the compliance/reporting requirements need to be simplified for small businesses.**
- d) **The regulations do not contain any design or operational standards for which small businesses need to be accommodated.**
- e) **The Board did not consider exempting small businesses from any part of the regulation. It would not be consistent with the public health, safety or welfare to make exceptions to the regulations.**

(28) If data is the basis for this regulation, please provide a description of the data, explain in detail how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.

**No specific data formed the basis for this regulation. The regulation was needed to ensure public safety based on the incident that occurred in Massachusetts. The Board is merely enforcing industry standards set forth in the United States Pharmacopeia Chapters relevant to compounding. Attached is the table of contents from the USP Compounding Compendium which sets forth all of the relevant chapters of the USP.**

(29) Include a schedule for review of the regulation including:

A. The length of the public comment period: **30 days after publication as proposed.**

B. The date or dates on which any public meetings or hearings will be held: **The Board reviews all regulatory proposals at regularly scheduled board meetings. See item (30) below for a schedule of meeting dates.**

C. The expected date of delivery of the final-form regulation: **Fall 2017.**

D. The expected effective date of the final-form regulation: **Upon publication as final.**

E. The expected date by which compliance with the final-form regulation will be required: **Upon publication as final.**

F. The expected date by which required permits, licenses or other approvals must be obtained: **N/A**

(30) Describe the plan developed for evaluating the continuing effectiveness of the regulations after its implementation.

**The Board continually reviews the efficacy of its regulations, as part of its annual review process under Executive Order 1996-1. The Board reviews its regulatory proposals at regularly scheduled monthly public meetings. The Board will meet on the following remaining dates in 2017: March 7, April 18, May 31, July 11, August 22, October 3 and November 28; and these dates in 2018: January 10, February 27, April 10, May 22, July 10, August 21, October 2 and November 27.**

PA STATE BOARD OF PHARMACY  
 PO Box 2649  
 Harrisburg, PA 17105-2649  
 (717) 783-7156 (PHONE)  
 • (717) 787-7769 (FAX)

FACILITY

LICENSE

License No

Profession: Pharmacy

License Type: Pharmacy

Name	License No	License Type	Status	Type
		Pharmacist	Active	Business Relationship

Inspection Type:	03-New Business
Inspection Date:	
Result:	Pass

Notes:

Remarks:

Checklist Results	
QUESTIONS	
Question	Answer
1. Are all licenses current and posted?	Yes
2. Are there signed and dated protocols for each pharmacy technician?	Yes
Number of pharmacy technicians employed:	0
3. Are prescription files properly maintained? (electronic files are acceptable)	Yes
4. Are outdated drugs appropriately removed from active stock?	Yes
5. Does the pharmacy have adequate equipment and supplies to enable it to properly prepare and dispense consistent with the pharmacy's scope of practice?	Yes
6. Is there a refrigerator with temperature monitoring for drug storage only?	Yes
7. Are current copies of all Federal, State, and Board statutes and regulations pertaining to pharmacy practice available? (Internet access is acceptable)	Yes
8. Is hot and cold water available in the prescription area?	Yes
9. Do labels have all the required information and match the license record?	Yes
10. Are transferred prescriptions properly recorded?	Yes
11. Are all prescriptions verified by registered pharmacists?	Yes
12. Is the name or initials of the dispensing pharmacist noted on the prescriptions?	Yes
13. Have any automated medication systems been properly validated?	N/A
14. Are there policies and procedures for the operation of any automated medication systems?	N/A
15. Is there a program for quality assurance for any automated medication systems?	N/A
16. Does the pharmacy meet all security requirements?	Yes
17. Are the required records maintained for the administration of injectable medications, biologicals, or immunizations?	N/A
18. Is the pharmacy in compliance with all sanitation, cleanliness, maintenance, and construction requirements?	Yes
19. Are Schedule II drugs dispersed throughout the stock or securely locked in a substantially constructed cabinet?	Yes
20. Is the generic equivalent sign and list of commonly used equivalents properly posted?	Yes

## NEW PHARMACY INSPECTION FORM QUESTIONS

- |     |  |     |
|-----|--|-----|
| 21. | Do you currently engage in the sterile compounding of drug products?   | Y/N |
| 22. | If engaged in sterile compounding, do you have records establishing that new employees have been trained and evaluated in the theoretical principles and practical skills of aseptic manipulations?  | Y/N |
| 23. | If engaged in sterile compounding, do you have records establishing that current employees practicing high-risk sterile compounding have been trained and evaluated in the theoretical principles and practical skills of aseptic manipulations on a semiannual basis?       | Y/N |
| 24. | If engaged in sterile compounding, do you have records establishing that current employees practicing low to medium-risk sterile compounding have been trained and evaluated in the theoretical principles and practical skills of aseptic manipulations on an annual basis? | Y/N |
| 25. | If engaged in sterile compounding, do you have records establishing that new employees practicing have been trained and evaluated regarding Media-Fill Challenge Testing?  | Y/N |
| 26. | If engaged in sterile compounding, do you have records establishing that current employees practicing high-risk sterile compounding have been trained and evaluated regarding Media-Fill Challenge Testing on a semiannual basis?  | Y/N |
| 27. | If engaged in sterile compounding, do you have records establishing that current employees practicing low to medium-risk sterile compounding have been trained and evaluated regarding Media-Fill Challenge Testing on a semiannual basis?                                   | Y/N |
| 28. | If engaged in sterile compounding, do you have records establishing that new employees practicing have been trained and evaluated regarding Hand Hygiene and Garbing Practices?  | Y/N |
| 29. | If engaged in sterile compounding, do you have records establishing that current employees practicing high-risk sterile compounding have been trained and evaluated regarding Hand Hygiene and Garbing Practices on a semiannual basis?                                      | Y/N |
| 30. | If engaged in sterile compounding, do you have records establishing that current employees practicing low to medium-risk sterile compounding have been trained and evaluated regarding Hand Hygiene and Garbing Practices on a semiannual basis?                             | Y/N |

31. If engaged in sterile compounding, do you have records establishing that new employees practicing have been trained and evaluated regarding Gloved Fingertip Sampling? Y/N
32. If engaged in sterile compounding, do you have records establishing that current employees practicing high-risk sterile compounding have been trained and evaluated regarding Gloved Fingertip Sampling on a semiannual basis? Y/N
33. If engaged in sterile compounding, do you have records establishing that current employees practicing low to medium-risk sterile compounding have been trained and evaluated regarding Gloved Fingertip Sampling on a semiannual basis? Y/N
34. If engaged in sterile compounding, do you have a Certified ISO Class 5 Compounding Area that has been certified no less than every six (6) months or upon any changes to the area? Y/N
35. If engaged in sterile compounding, do you have a Certified ISO Class 7 Buffer Area that has been certified no less than every six (6) months or upon any changes to the area? Y/N
36. Are the Buffer and Ante-Areas appropriately maintained? Y/N
37. Are pressure gauges or velocity meter installed? Y/N
38. Do the pharmacy records indicate that pressure differentials have been logged At least every work shift or by a continuous recording device? Y/N
39. Does the pharmacy have an environmental viable airborne particle testing plan in place? Y/N
40. Do the pharmacy records indicate that the daily cleaning and disinfection practices have been performed? Y/N
41. Do the pharmacy records indicate that the monthly cleaning and disinfection practices have been performed? Y/N
42. Does the pharmacy have an approved standard operating procedure (SOP) in place to ensure the quality of the environment? Y/N
43. Do the labels on the finished compounded drug products have the required Information for safe use? Y/N

Pharmacy Compounding of Human  
Drug Products Under Section 503A  
of the Federal Food, Drug, and  
Cosmetic Act

**Guidance**

U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)

June 2016  
Compounding and Related Documents  
Revision 2

# Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act

## Guidance

*Additional copies are available from:*

*Office of Communications  
Division of Drug Information, WO51, Room 2201  
Center for Drug Evaluation and Research  
Food and Drug Administration  
10903 New Hampshire Ave., Silver Spring, MD 20993  
Phone: 301-796-3400; Fax: 301-847-8714  
druginfo@fda.hhs.gov*

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>

or

*Office of Policy  
Office of the Commissioner  
Food and Drug Administration  
10903 New Hampshire Ave.  
Silver Spring, MD 20993  
Phone: 301-796-4830*

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)**

**June 2016  
Compounding and Related Documents  
Revision 2**

*Contains Nonbinding Recommendations*

**TABLE OF CONTENTS**

<b>I. INTRODUCTION</b> .....	<b>1</b>
<b>II. BACKGROUND</b> .....	<b>2</b>
<b>III. POLICY</b> .....	<b>2</b>
<b>A. Conditions of Section 503A</b> .....	<b>3</b>
<b>B. Provisions of Section 503A That Require Regulations or Other FDA Actions</b> .....	<b>5</b>
<b>IV. GUIDANCE ON REGULATORY ACTION</b> .....	<b>6</b>
<b>A. Requirements Applicable to Drug Products That Meet the Conditions of Section 503A</b> .....	<b>6</b>
<b>B. Enforcement Action When a Drug Does Not Meet the Conditions of Section 503A</b> .....	<b>7</b>
<b>C. Enforcement Approach</b> .....	<b>8</b>

**Guidance<sup>1</sup>**  
**Pharmacy Compounding of Human Drug Products Under Section  
503A of the Federal Food, Drug, and Cosmetic Act**

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create any rights for or on any person and is not binding on FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed in the title page.

**I. INTRODUCTION**

This guidance announces FDA's intention with regard to enforcement of section 503A of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 353a) to regulate entities that compound drugs, now that section 503A has been amended by Congress to remove the advertising and solicitation provisions that were held unconstitutional by the U.S. Supreme Court in 2002 (see section II below). Several parts of section 503A require rulemaking and consultation with a Pharmacy Compounding Advisory Committee to implement. This guidance explains how the provisions will be applied pending those consultations and rulemaking. This guidance also describes some of the possible enforcement actions FDA can bring against individuals or firms that compound drugs in violation of the FD&C Act.

This guidance does not apply to registered *outsourcing facilities* under section 503B of the FD&C Act.<sup>2</sup> Guidance for outsourcing facilities will be issued separately.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

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<sup>1</sup> This guidance was prepared by the Office of Compliance, Center for Drug Evaluation and Research at the Food and Drug Administration.

<sup>2</sup> Title I of the Drug Quality and Security Act created a new section 503B of the FD&C Act, entitled "Outsourcing Facilities." See Pub. L. No. 113-54, § 102(a), 127 Stat. 587, 587-588 (2013).

## *Contains Nonbinding Recommendations*

### II. BACKGROUND

Section 503A was added to the FD&C Act by the Food and Drug Administration Modernization Act of 1997 (Public Law 105-115) (the Modernization Act). Section 503A describes the conditions that must be satisfied for drug products compounded by a licensed pharmacist or licensed physician to be exempt from the following three sections of the FD&C Act: (1) section 501(a)(2)(B) (concerning current good manufacturing practice); (2) section 502(f)(1) (concerning the labeling of drugs with adequate directions for use); and (3) section 505 (concerning the approval of drugs under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)).<sup>3</sup>

Previously, the conditions of section 503A of the FD&C Act also included restrictions on the advertising or promotion of the compounding of any particular drug, class of drug, or type of drug and the solicitation of prescriptions for compounded drugs. These provisions were challenged in court and held unconstitutional by the U.S. Supreme Court in 2002.<sup>4</sup> Following that decision, in May 2002 FDA issued a compliance policy guide entitled *Pharmacy Compounding* (May 2002 CPG), which described how FDA intended “to address pharmacy compounding of human drugs in the immediate future” as a result of the Supreme Court decision.<sup>5</sup> In 2013, section 503A was amended by the Drug Quality and Security Act (DQSA)<sup>6</sup> to remove the advertising, promotion, and solicitation provisions. As a result, the May 2002 CPG is no longer relevant, and it is necessary to explain FDA’s current thinking with regard to section 503A.

The *Federal Register* notice announcing the availability of the draft version of this guidance withdrew the May 2002 CPG as well as the November 1998 guidance for industry entitled *Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act*.<sup>7</sup>

### III. POLICY

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<sup>3</sup> Section 503A of the FD&C Act and this guidance do not apply to positron emission tomography (PET) drugs as defined in section 201(ii) of the FD&C Act or radiopharmaceuticals (see section 503A(e) of the FD&C Act). Section 503A(e) specifically states that section 503A does not apply to radiopharmaceuticals or to PET drugs as defined in section 201(ii). PET drugs are subject to the current good manufacturing practice requirements of 21 CFR part 212. Section 503A also does not apply to drugs intended for use in animals. The statutory and regulatory provisions governing the compounding of human drug products differ from those governing the compounding of animal drug products. All relevant statutory and regulatory requirements relating to the compounding of animal drug products remain in effect, subject to the requirements of section 512 of the FD&C Act (21 U.S.C. 360b) and 21 CFR part 530.

<sup>4</sup> See *Thompson v. Western States Med. Ctr.*, 535 U.S. 357 (2002).

<sup>5</sup> See 67 FR 39,409 (June 7, 2002).

<sup>6</sup> See Pub. L. No. 113-54 (2013).

<sup>7</sup> 78 FR 72,901 (Dec. 4, 2013).

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A drug product intended for use in humans that is compounded in compliance with section 503A and its associated regulations is exempt from the requirements in sections 501(a)(2)(B), 502(f)(1), and 505 of the FD&C Act. However, all other applicable provisions of the FD&C Act remain in effect for compounded drugs, even if the conditions of section 503A are met.

FDA expects state boards of pharmacy to continue their oversight and regulation of the practice of pharmacy, including pharmacy compounding. FDA also intends to continue to cooperate with state authorities to address pharmacy activities that may be violative of the FD&C Act, including section 503A. FDA's enforcement approach with respect to such violations is described in section IV.C., below.

#### **A. Conditions of Section 503A**

Under section 503A of the FD&C Act, a compounded drug product is exempt from sections 501(a)(2)(B), 502(f)(1), and 505 of the FD&C Act if it meets the conditions of section 503A of the FD&C Act. Specifically, the compounded drug product qualifies for the exemptions if:

1. The drug product is compounded for an identified individual patient based on the receipt of a valid prescription order, or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient (section 503A(a) of the FD&C Act).
2. The compounding of the drug product is performed:
  - By a licensed pharmacist in a state licensed pharmacy or a Federal facility, or by a licensed physician on the prescription order for an individual patient made by a licensed physician or other licensed practitioner authorized by state law to prescribe drugs; or
  - By a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient and:
    - is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the human drug product; and
    - those orders have been generated solely within an established relationship between the licensed pharmacist or licensed physician and either such patient for whom the prescription order will be provided or the physician or other licensed practitioner who will write such prescription order (sections 503A(a)(1) and (2) of the FD&C Act).
3. The drug product is compounded in compliance with the United States Pharmacopoeia (USP) chapters on pharmacy compounding<sup>8</sup> using bulk drug substances, as defined in 21 CFR 207.3(a)(4), that comply with the standards of an applicable USP or National Formulary (NF) monograph, if one exists.

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<sup>8</sup> After the Modernization Act was enacted in 1997, the USP moved its chapter on pharmacy compounding to chapter <795> and added chapter <797>, which specifically addresses sterile compounding and is referenced in chapter <795>.

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If such a monograph does not exist, the drug substance(s) must be a component of an FDA-approved human drug product. If a monograph does not exist and the drug substance is not a component of an FDA-approved human drug product, it must appear on a list of bulk drug substances for use in compounding developed by FDA through regulation (section 503A(b)(1)(A)(i) of the FD&C Act). See section III.B.2 below for the interim policy for this provision.

4. The drug product is compounded using bulk drug substances that are manufactured by an establishment that is registered under section 510 of the FD&C Act (including a foreign establishment that is registered under section 510(i) of the FD&C Act) (section 503A(b)(1)(A)(ii) of the FD&C Act).
5. The drug product is compounded using bulk drug substances that are accompanied by valid certificates of analysis for each bulk drug substance (section 503A(b)(1)(A)(iii) of the FD&C Act).
6. The drug product is compounded using ingredients (other than bulk drug substances) that comply with the standards of an applicable USP or NF monograph, if one exists, and the USP chapters on pharmacy compounding<sup>9</sup> (section 503A(b)(1)(B) of the FD&C Act).
7. The drug product does not appear on the list, published at 21 CFR 216.24, that includes drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective (section 503A(b)(1)(C) of the FD&C Act). See section III.B.1 below.
8. The licensed pharmacist or licensed physician does not compound regularly or in inordinate amounts any drug products that are essentially copies of commercially available drug products (section 503A(b)(1)(D) of the FD&C Act).
9. The drug product is not a drug product identified by FDA by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product (section 503A(b)(3)(A) of the FD&C Act). See section III.B.3 below.
10. The drug product is compounded in a state that has entered into a memorandum of understanding (MOU) with FDA that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a state agency of complaints relating to compounded drug products distributed outside such state; or, in states that have not entered into such an MOU with FDA, the licensed pharmacist, licensed pharmacy, or licensed physician does not distribute, or cause to be distributed, compounded drug products out of the state in which they are compounded, more than 5% of the total prescription orders dispensed or distributed by such pharmacy

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<sup>9</sup> *Id.*

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or physician (sections 503A(b)(3)(B)(i) & (ii) of the FD&C Act). See section III.B.4 below for the interim policy for this provision.

### **B. Provisions of Section 503A That Require Regulations or Other FDA Actions**

Specific provisions of section 503A of the FD&C Act require rulemaking or other action by FDA. FDA's policy related to these specific provisions is described below.

#### *1. Withdrawn or Removed List*

FDA promulgated a final rule, codified at 21 CFR 216.24, which lists drug products that cannot be compounded because they have been withdrawn or removed from the market because the drug products or components of the drug products have been found to be unsafe or not effective. *FDA intends to update this list periodically, and expects compounders to comply with the list as it currently exists and with any final updates.*

#### *2. Bulk Drug Substances List*

Section 503A(b)(1)(A)(i)(III) of the FD&C Act provides that a drug product can be compounded using bulk drug substances that do not have an applicable USP or NF monograph (section 503A(b)(1)(A)(i)(I) of the FD&C Act) and are not components of FDA-approved drugs (section 503A(b)(1)(A)(i)(II) of the FD&C Act) if the bulk drug substances appear on a list developed by FDA and issued through regulation.

In the Federal Register of April 7, 1998 (63 FR 17,011), FDA invited all interested persons to nominate bulk drug substances for inclusion on the list. In the Federal Register of January 7, 1999 (64 FR 996), FDA published a proposed rule listing bulk drug substances that can be used in pharmacy compounding. In the Federal Register of December 4, 2013 (78 FR 72,841), FDA published a notice withdrawing the 1999 proposed rule and inviting all interested persons to nominate bulk drug substances for inclusion on a list of bulk drug substances that can be used for compounding under section 503A of the FD&C Act. FDA's interim policy concerning bulk drug substances that are not components of drugs approved under section 505 of the FD&C Act or that are not the subject of applicable USP or NF monographs can be found in the guidance, *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug and Cosmetic Act*.

#### *3. "Demonstrable Difficulties" for Compounding*

Under section 503A(b)(3)(A) of the FD&C Act, a compounded drug product would not qualify for the exemptions provided in subsection (a) if it is identified by FDA through regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of the drug product. In the *Federal Register* of December 4, 2013 (78 FR 72,840), FDA published a notice inviting all interested persons to nominate drug products or categories of drug products for inclusion on a list of drug products that present demonstrable difficulties for compounding (difficult-to-compound list). This provision is not enforceable until FDA promulgates an implementing regulation.

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### *4. Memorandum of Understanding Between FDA and the States*

Section 503A(b)(3) of the FD&C Act states that FDA, in consultation with the National Association of Boards of Pharmacy (NABP) will develop a standard MOU for use between FDA and the states that will address the interstate distribution of inordinate amounts of compounded drug products and provide for appropriate investigation by a state agency of complaints relating to compounded drug products distributed outside that state. On January 21, 1999, FDA published a notice in the *Federal Register* announcing the availability of a draft standard MOU, developed in consultation with the NABP. This draft MOU was not finalized. FDA intends to publish a new draft MOU for comment that will replace the January 1999 draft.

Under section 503A(b)(3)(B)(ii), an individual or firm in a state that does not enter into an MOU with FDA that distributes, or causes to be distributed, compounded drug products out of the state in which they are compounded, can compound for interstate distribution outside the state only 5% of the total prescription orders dispensed or distributed by the individual or firm. FDA does not intend to enforce the 5% limit on interstate distribution until after FDA has finalized an MOU and made it available to the states for their consideration and signature. The *Federal Register* notice that will announce the availability of the draft MOU will specify a time period during which the MOU will be made available to the states to sign. After this time period expires, FDA intends to begin enforcing the 5% limit in states that have not signed the MOU.

## **IV. GUIDANCE ON REGULATORY ACTION**

### **A. Requirements Applicable to Drug Products that Meet the Conditions of Section 503A**

As stated above, a compounded drug product intended for use in humans that meets the conditions of section 503A of the FD&C Act and its associated regulations is exempt from the requirements under sections 501(a)(2)(B), 502(f)(1), and 505 of the FD&C Act.

However, individuals and firms may be subject to a warning letter, seizure of product, injunction, and/or criminal prosecution for violations of other requirements of the FD&C Act. Such violations may include, but are not limited to, the following:

1. The drug product must not consist in whole or in part of any filthy, putrid, or decomposed substance, or be prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health. (Sections 501(a)(1) and (a)(2)(A) of the FD&C Act)
2. If the drug product purports to be a drug that is recognized in an official compendium, its strength must not differ from, and its quality or purity must not fall below, the standards set forth in the compendium, unless the difference is plainly stated on its label. (Section 501(b) of the FD&C Act)

### *Contains Nonbinding Recommendations*

3. For a drug product not subject to section 501(b) of the FD&C Act, the drug's strength must not differ from, and its quality or purity must not fall below, that which it purports to have. (Section 501(c) of the FD&C Act)
4. If the drug product purports to be a drug that is recognized in an official compendium, it must be packaged and labeled as prescribed in the compendium. (Section 502(g) of the FD&C Act)
5. The drug product's labeling, advertising, and promotion must not be false or misleading. (Sections 502(a), 502(bb),<sup>10</sup> and 201(n) of the FD&C Act)

#### **B. Enforcement Action When a Drug Does Not Meet the Conditions of Section 503A**

If FDA determines that an individual or firm compounds a drug product that does not meet the conditions of section 503A, then in addition to the violations listed above in section IV.A., the individual or firm that compounds the drug product may also be subject to a warning letter, seizure of product, injunction, and/or criminal prosecution for violations of sections 501(a)(2)(B), 502(f)(1), and 505 of the FD&C Act.<sup>11</sup> Such violations may include, but are not limited to, the following:

##### *1. Producing Adulterated Drugs*

In accordance with section 501(a)(2)(B) of the FD&C Act and 21 CFR parts 210 and 211, the methods used in, and the facilities and controls used for, the manufacture, processing, packing, and holding of a drug must conform with current good manufacturing practice (CGMP) requirements. If an individual or firm compounds any drug products that do not meet the conditions of section 503A of the FD&C Act, those drug products would be subject to CGMP requirements.

##### *2. Producing Unapproved New Drugs*

In accordance with section 505(a) of the FD&C Act, an individual or firm must not introduce or deliver for introduction into interstate commerce any new drug unless an approved NDA or ANDA is in effect for that drug product. If an individual or firm compounds any drug products that do not meet the conditions of section 503A of the FD&C Act, those drug products would be subject to the new drug approval requirements.

##### *3. Misbranded Drugs*

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<sup>10</sup> Section 502(bb) was added to the FD&C Act by section 103(b) of the DQSA.

<sup>11</sup> See *Medical Ctr. Pharm. v. Mukasey*, 536 F.3d 383, 405 (5th Cir. 2008) ("compounded drugs are in fact 'new drugs' as defined by [21 U.S.C.] § 321(p) but are exempt from the requirements of [21 U.S.C.] §§ 351(a)(2)(B), 352(f)(1), and 355 if and only if they comply with the conditions set forth in [21 U.S.C.] § 353a.").

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In accordance with section 502(f)(1) of the FD&C Act and 21 CFR part 201.5, drug products that are not labeled with adequate directions for use are misbranded. If an individual or firm compounds any drug products that do not meet the conditions of section 503A of the FD&C Act, those drug products would be subject to the requirements for adequate directions for use.

In addition to sections 501(a)(2)(B), 502(f)(1), and 505 of the FD&C Act, an individual or firm that compounds any drug products that do not meet the conditions of section 503A of the FD&C Act would be subject to the requirements listed in section IV.A, above, as well as other requirements of the FD&C Act and FDA regulations.

#### **C. Enforcement Approach**

Generally, FDA expects to employ a risk-based enforcement approach with respect to violative compounded drugs, giving the highest enforcement priority to compounded drugs and violations of the FD&C Act and FDA regulations that pose the greatest public health risks. However, FDA emphasizes that it need not identify a particular safety problem before pursuing enforcement action.

Effective: November 27, 2013

21 U.S.C.A. § 353a

§ 353a. Pharmacy compounding

Currentness

**(a) In general**

Sections 351(a)(2)(B), 352(f)(1), and 355 of this title shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding--

**(1)** is by--

**(A)** a licensed pharmacist in a State licensed pharmacy or a Federal facility, or

**(B)** a licensed physician,

on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or

**(2)(A)** is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and

**(B)** is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between--

**(i)** the licensed pharmacist or licensed physician; and

**(ii)(I)** such individual patient for whom the prescription order will be provided; or

**(II)** the physician or other licensed practitioner who will write such prescription order.

**(b) Compounded drug**

**(1) Licensed pharmacist and licensed physician**

A drug product may be compounded under subsection (a) of this section if the licensed pharmacist or licensed physician--

**(A)** compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations--

**(i)** that--

**(I)** comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or

(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (c) of this section;

(ii) that are manufactured by an establishment that is registered under section 360 of this title (including a foreign establishment that is registered under section 360(i) of this title); and

(iii) that are accompanied by valid certificates of analysis for each bulk drug substance;

(B) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(C) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective; and

(D) does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.

## **(2) Definition**

For purposes of paragraph (1)(D), the term "essentially a copy of a commercially available drug product" does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product.

## **(3) Drug product**

A drug product may be compounded under subsection (a) only if--

(A) such drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and

(B) such drug product is compounded in a State--

(i) that has entered into a memorandum of understanding with the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State; or

(ii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities

that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician.

The Secretary shall, in consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by the States in complying with subparagraph (B)(i).

**(c) Regulations**

**(1) In general**

The Secretary shall issue regulations to implement this section. Before issuing regulations to implement subsections (b)(1)(A)(i)(III), (b)(1)(C), or (b)(3)(A) of this section, the Secretary shall convene and consult an advisory committee on compounding unless the Secretary determines that the issuance of such regulations before consultation is necessary to protect the public health. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopoeia, pharmacy, physician, and consumer organizations, and other experts selected by the Secretary.

**(2) Limiting compounding**

The Secretary, in consultation with the United States Pharmacopoeia Convention, Incorporated, shall promulgate regulations identifying drug substances that may be used in compounding under subsection (b)(1)(A)(i)(III) of this section for which a monograph does not exist or which are not components of drug products approved by the Secretary. The Secretary shall include in the regulation the criteria for such substances, which shall include historical use, reports in peer reviewed medical literature, or other criteria the Secretary may identify.

**(d) Application**

This section shall not apply to--

- (1) compounded positron emission tomography drugs as defined in section 321(ii) of this title; or
- (2) radiopharmaceuticals.

**(e) "Compounding" defined**

As used in this section, 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.

**(f) Redesignated (e)**

**CREDIT(S)**

(June 25, 1938, c. 675, § 503A, as added Nov. 21, 1997, Pub.L. 105-115, Title I, § 127(a), 111 Stat. 2328; amended Pub.L. 113-54, Title I, § 106(a), Nov. 27, 2013, 127 Stat. 598.)

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(AGENCY)

BY: *Marisa H. Z. Lehr*

DOCUMENT/FISCAL NOTE NO. 16A-5419

DEC 21 2016

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DATE OF ADOPTION: \_\_\_\_\_

BY: *Theresa M. Talbott*

Theresa M. Talbott, R.Ph.

OCT 14 2016

DATE OF APPROVAL

( Deputy General Counsel  
Strike inapplicable title)

TITLE: Chairperson  
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

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PROPOSED RULEMAKING

COMMONWEALTH OF PENNSYLVANIA  
DEPARTMENT OF STATE  
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS  
STATE BOARD OF PHARMACY  
49 PA. CODE, CHAPTER 27

§§ 27.1, 27.12, 27.601—27.624

COMPOUNDING

The State Board of Pharmacy (Board) proposes to amend §§ 27.1 and 27.12 (relating to definitions; and practice of pharmacy and delegation of duties), and to add §§ 27.601—27.624 (relating to compounding), to read as set forth in Annex A.

*Effective date*

The amendments will be effective upon publication of the final-form rulemaking in the *Pennsylvania Bulletin*.

*Statutory Authority*

The amendments are 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 and Need for the Amendment*

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 U.S. Food and Drug Administration (FDA). Through careful review and input from stakeholders, the Board now proposes to update its regulations to incorporate developments and improvements in the profession's safe, sterile practices and procedures for the compounding of pharmaceutical products for patients.

*Description of Proposed Amendments*

Section 27.1 (definitions)

The Board finds it necessary to define the acronym FDA to mean the U.S. Food and Drug Administration, a division of the U.S. Department of Health and Human Services; and to define the acronym USP to refer to the United States Pharmacopeia, a compendium of drug information published by the United States Pharmacopeial Convention.

Section 27.12 (practice of pharmacy and delegation of duties)

The Board proposes to amend this section to permit a pharmacy technician to assist the pharmacist in the compounding of drug products.

Addition of provisions on compounding

The proposed rulemaking would add 24 new sections to the Board's regulations to set forth standards for the compounding of pharmaceutical products.

Proposed § 27.601 (relating to compounding of preparations) would require that all compounding shall be done in accordance with the current version of the United States Pharmacopeia (USP) chapters governing compounding, which is consistent with Federal law. The most relevant chapters at the present time are Chapters <795> and <797> (relating to pharmaceutical compounding—nonsterile preparations; and pharmaceutical compounding – sterile preparations), however there are other chapters of the USP that are relevant and they are subject to change and for that reason, the Board chose simply to refer to the current version of the USP chapters governing compounding. The Federal Food and Drug Administration (FDA) requires that compounded drug products conform with USP’s standards in accordance with section 503a of the Federal Food, Drug and Cosmetic Act (21 U.S.C.A. § 353a) relating to pharmacy compounding. Compounded drugs that do not conform to the USP chapters on compounding may be deemed adulterated or misbranded, which would make them commercially unavailable for consumption. On November 27, 2013, the Federal Drug Quality and Security Act (DQSA) was enacted. Title I of the DQSA enacted the Compounding Quality Act, which included important provisions relating to the FDA’s oversight of compounding of human drugs, and enhanced communication with state Boards of Pharmacy. In June of 2016, the FDA issued a guidance document, “Pharmacy Compounding of Human Drug Products under Section 503a of the Federal Food, Drug, and Cosmetic Act – Guidance” that is intended to explain how the FDA will interpret section 503a while it engages in the rulemaking process. It is available for review on the FDA’s website at the following link: (<http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm469119.pdf>). Because the FDA requires that pharmacies follow the USP chapters on compounding, the Board proposes to likewise require all compounding by pharmacies in this Commonwealth to comply with the USP.

Proposed § 27.602 (relating to compounding commercially available product) would permit compounding of drug products that are commercially available in the marketplace if the compounded product is changed to produce for a patient a significant medical difference, as authorized by the prescriber, between the compounded drug and the comparable commercially available drug product, or if use of the compounded product is in the best interest of the patient. An example of a significant medical difference would include the removal of a dye to which the patient is allergic.

Proposed § 27.603 (relating to bulk drug substances) addresses the use of bulk drug substances for compounding drugs, including the required registration and certification of analysis of such substances.

Proposed § 27.604 (relating to dispensing compounded drugs) addresses dispensing a compounded drug and the circumstances under which compounding is permitted prior to the pharmacist’s receipt of a valid prescription for a particular patient, based on that patient’s prescription history. Bulk compounding shall comply with the requirements of §§ 27.603 and 27.623 (relating to production record).

Proposed § 27.605 (relating to resale of compounded drug products) would prohibit the wholesale distribution of compounded drug products to other pharmacies, commercial entities or prescribers except in certain circumstances relating to medical practitioners. Pharmacists may

only compound nonprescription over-the-counter products for sale pursuant to a prescription, and shall comply with FDA labeling requirements and restrictions.

Proposed § 27.606 (relating to compounding prohibited) would prohibit compounding of certain FDA-identified drugs and restricts the compounding of certain commercially available products beyond that otherwise permitted under § 27.602.

Proposed § 27.607 (relating to pharmacist responsibilities) would set forth the pharmacist's responsibilities regarding compounding practice.

Proposed § 27.608 (relating to protective apparel) would specify the clothing required to be worn by pharmacy personnel engaged in compounding and, in certain circumstances involving sterile pharmaceuticals, additional gowning components required by the USP.

Proposed § 27.609 (relating to drug compounding facilities requirements) would set forth the requirements regarding facility conditions, to minimize the possibility of contamination or decomposition.

Proposed § 27.610 (relating to equipment) would require that the equipment used in compounding of drug products must comply with the USP chapters on equipment.

Proposed § 27.611 (relating to equipment maintenance) addresses the cleaning and sanitizing of the equipment and utensils used for compounding prior to their use to prevent contamination of the drug product.

Proposed § 27.612 (relating to specialized equipment) would provide for measures including the use of dedicated equipment or the meticulous cleaning of contaminated equipment prior to its return to inventory to prevent cross-contamination.

Proposed § 27.613 (relating to use of automated equipment) would require the routine inspection and calibration of equipment used in compounding and the maintenance of the related documentation of these tasks.

Proposed § 27.614 (relating to control of containers and closures) would require drug product containers and closures to meet the requirements of the USP chapters related to drug product containers and closures.

Proposed § 27.615 (relating to storage) would require that components, bulk drug substances and other materials used in compounding drug products shall be stored in accordance with the USP storage requirements. It also describes the requirement that the composition of the drugs, containers or closures permit the appropriate handling and storage, the cleaning of the work area, and the rotating of those items to ensure that the oldest stock of each is utilized first.

Proposed § 27.616 (relating to drug compounding controls) expressly assigns the responsibility of accountability for quality control to the compounding pharmacist.

Proposed § 27.617 (relating to standard operating procedures) would require the establishment of standard operating procedures implementing the applicable USP chapters to ensure the safety, identity, strength, quality and purity of the finished product. Subsection (b) requires standard operating procedures that are designed to prevent microbiological contamination of purportedly sterile compounded drug products. Subsection (c) requires standard operating procedures relating to the tests or examinations to be conducted designed to ensure the reasonable uniformity and integrity of compounded drug products.

Proposed § 27.618 (relating to accuracy) provides additional quantity and quality control procedures regarding weights, measures, subdivision and container labels.

Proposed § 27.619 (relating to production record) specifies the necessary contents and retention of production records for each drug product compounded for an individual patient, as to be distinguished from the production records for each batch of drug product compounded (as required by proposed § 27.624 (relating to production record for drugs compounded in bulk quantities)).

Proposed § 27.620 (relating to label information required) itemizes the specific information required on the label affixed to the dispensing container, or on the container itself, of any compounded drug product dispensed by a pharmacy pursuant to a prescription or drug order.

Proposed § 27.621 (relating to compounding records) provides that all records required by this chapter shall be retained as original records and shall be readily available at the pharmacy for inspection and photocopying by 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 by § 27.18 (b) (relating to standards of practice).

The final three sections relate specifically to bulk compounding. Proposed § 27.622 (relating to master formula record) specifies the necessary contents of the master formula record for each drug product compounded in bulk quantity. Proposed § 27.623 (relating to production record for drugs compounded in bulk quantities) specifies the necessary contents and retention of production records for each batch of drug product compounded. Finally, proposed § 27.624 (relating to label information) itemizes the specific information to be recorded on the label affixed to the container of each batch of drug product compounded.

#### *Fiscal Impact*

The proposed amendments 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 the 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.

### *Paperwork Requirements*

The proposed amendments will impose additional paperwork requirements on the regulated community. Pharmacies that engage in compounding of pharmaceuticals will have to keep records on file as required by the regulations. The Board will need to alter its inspection forms to capture information relating to compounding, but no other paperwork requirements would be imposed on the Commonwealth.

### *Sunset Date*

The Board continuously monitors the effectiveness of its regulations. Therefore, no sunset date has been assigned.

### *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 this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the Senate Consumer Protection and Professional Licensure Committee and the House Professional Licensure Committee. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey comments, recommendations or objections to the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections shall specify the regulatory review criteria which have not been met. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Board, the General Assembly and the Governor of comments, recommendations or objections raised.

### *Public Comment*

Interested persons are invited to submit written comments, suggestions or objections regarding this proposed rulemaking to Board Counsel, State Board of Pharmacy, by mail at P.O. Box 69523, Harrisburg, PA 17106-9523, or by email at RA-STRegulatoryCounsel@pa.gov, within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*. Please reference No. 16A-5419 (Compounding), when submitting comments.

Janet Getzey Hart, R.Ph.  
Chairperson

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:

\* \* \* \* \*

FDA—The U.S. Food and Drug Administration, a division of the U.S. Department of Health and Human Services.

\* \* \* \* \*

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

\* \* \* \* \*

§ 27.12. Practice of pharmacy and delegation of duties.

\* \* \* \* \*

(d) *Pharmacy technicians.*

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

\* \* \* \* \*

(vii) Assist the pharmacist in the compounding of drug products.

\* \* \* \* \*

## COMPOUNDING

### § 27.601. Compounding of preparations.

The compounding of sterile and non-sterile preparations shall be done in accordance with the current version of the USP chapters governing compounding.

### § 27.602. Compounding commercially available product.

Based on the existence of a pharmacist/patient/prescriber relationship and the presentation of a valid prescription or drug order, pharmacists may compound, for an individual patient, drug products that are commercially available in the marketplace, if one of the following conditions is met:

(1) The compounded preparation is changed to produce for that patient a significant medical difference, as authorized by the prescriber, between the compounded drug and the comparable commercially available drug product. An example of “significant medical difference” would include the removal of a dye for a medical reason such as an allergic reaction.

(2) Use of the compounded preparation is in the best interest of the patient.

### § 27.603. Bulk drug substances.

Bulk drug substances to be used in compounding drugs must meet one of the following:

(1) When a monograph exists, bulk drug substances must comply with the applicable USP or National Formulary (NF) monograph and the USP chapters on pharmaceutical compounding.

(2) If not subject to a monograph, bulk drug substances must meet one of the following:

(i) The bulk drug substances are ingredients of drugs that the FDA has approved.

(ii) The bulk drug substances appear on the FDA list of approved bulk drug substances not subject to a monograph.

(iii) Peer-reviewed medical literature supports and, in the professional judgment of the pharmacist and prescriber, demonstrates the safety and effectiveness of the bulk drug substances.

**§ 27.604. Dispensing compounded drugs.**

A compounded drug shall only be dispensed pursuant to a prescription or drug order by the prescriber for a specific patient. Pharmacists may compound drugs in anticipation of receiving a valid prescription based on a history of receiving valid prescriptions generated solely within an established practitioner/patient/ pharmacist relationship. Bulk compounding shall comply with the requirements of §§ 27.603 and 27.623 (relating to bulk drug substances; and production record for drugs compounded in bulk quantities).

**§ 27.605. Resale of compounded drug products.**

(a) The wholesale distribution of compounded drug products to other pharmacies, commercial entities or prescribers is considered manufacturing and is prohibited, except for distribution to a medical practitioner to administer to an individual patient if the medical practitioner has an administrative system whereby the product can be tracked through the medical practitioner to the individual patient.

(b) Pharmacists may compound for sale over-the-counter products in which all components are nonprescription. However, the products may be compounded only pursuant to a prescription and shall comply with FDA labeling requirements and restrictions at 21 CFR Part 201 (relating to labeling).

**§ 27.606. Compounding prohibited.**

Pharmacists may not compound:

(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 at 21 CFR § 216.24 (relating to drug products withdrawn or removed from the market for reasons of safety or effectiveness).

(2) Drugs that are essentially copies of a commercially available drug product, except as provided in § 27.602 (relating to compounding commercially available product).

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

**§ 27.607. Pharmacist responsibilities.**

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

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

(2) Preparation and review of all compounding records to assure that no errors have 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 shall include conclusions and corrective action.

**§ 27.608. Protective apparel.**

Pharmacy personnel engaged in the compounding of drugs shall wear clean clothing appropriate to the operation being performed. Protective apparel, such as a coat or jacket, apron, or hand or arm coverings, shall be worn as necessary to protect drug products from contamination. For a sterile compounding operation involving one or more aseptic manipulations, sterile gowning components are necessary as required by the USP Chapter on sterile compounding.

**§ 27.609. Drug compounding facility requirements.**

Pharmacies engaged in compounding shall provide the following:

(1) A specifically designated area for the orderly placement of equipment and materials to be used to compound medications and to prevent mix-ups or contamination between components, containers, labels, in-process materials and finished drug products.

(2) Washing facilities, easily accessible to the compounding area of the pharmacy, including a sink with hot and cold running water, soap or detergent, and air driers or single use towels.

(3) Lighting, heating, ventilation, and air conditioning to prevent contamination or decomposition of components, in compliance with the USP provisions regarding facility requirements.

**§ 27.610. Equipment.**

Equipment used in the compounding of drug products shall comply with the USP chapters on equipment.

**§ 27.611. Equipment maintenance.**

Equipment and utensils used for compounding shall be cleaned and sanitized in accordance with the USP chapters on equipment maintenance prior to use to prevent contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond that desired.

**§ 27.612. Specialized equipment.**

If drug products with special precautions to prevent contamination are involved in a compounding operation, appropriate measures, including either the dedication of equipment for such operations or the meticulous cleaning of contaminated equipment prior to its return to inventory, shall be utilized to prevent cross-contamination.

**§ 27.613. Use of automated equipment.**

Automatic, mechanical, or electronic equipment, or other types of equipment or related systems may be used in the compounding of drug products. If such equipment is used, it must be inspected and calibrated in accordance with the manufacturer's recommendations to ensure proper performance. Documentation of inspection and calibration shall be kept on file for 2 years from the date of inspection and calibration.

**§ 27.614. Control of containers and closures.**

Drug product containers and closures shall meet the requirements of the USP chapters related to drug product containers and closures.

**§ 27.615. Storage.**

(a) Components, bulk drug substances and other materials used in the compounding of drug products shall be stored in accordance with the USP storage requirements.

(b) Components, bulk drug substances, drug product containers, closures, and bagged or boxed parts of drug product containers and closures used in the compounding of drug products must allow for:

(1) Handling and storage in a manner to prevent contamination and to permit inspection.

(2) Cleaning of the work area, including floors.

(3) Rotating of components, bulk drug substances, drug product containers and closures for use in compounding of drug products to ensure use of oldest stock first.

**§ 27.616. Drug compounding controls.**

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

**§ 27.617. Standard operating procedures required.**

(a) The pharmacist shall establish and implement standard operating procedures for the compounding of drug products in accordance with applicable USP chapters to ensure the safety, identity, strength, quality, and purity of the finished product. Such procedures shall include maintaining a listing of the bulk drug substances and components, their amounts in weight or volume, the order of bulk drug substance and component addition,

and a description of the compounding processes. All equipment, utensils, and the container closure system relevant to the sterility and stability of the intended use of the compounded drug product shall be listed.

(b) The pharmacist shall establish standard operating procedures in accordance with applicable USP chapters that are designed to prevent microbiological contamination of compounded drug products purported to be sterile, including validation of any sterilization process.

(c) To ensure the reasonable uniformity and integrity of compounded drug products, the pharmacist shall establish standard operating procedures that describe the tests or examinations to be conducted on the product being compounded. Control procedures shall include the following, as appropriate:

- (1) Capsule weight variation.
- (2) Adequacy of mixing to ensure uniformity and homogeneity.
- (3) Clarity, completeness, or pH of solutions.

**§ 27.618. Accuracy.**

(a) Components and bulk drug substances used in the compounding of drug products shall be accurately weighed, measured, or subdivided as appropriate. These operations shall be verified at each stage of the process to ensure that each weight or measure is correct as stated in the compounding procedures.

(b) If a component or bulk drug substance is removed from the original container and stored in another container, the new container shall be identified with the following:

- (1) Name.
- (2) Lot number.

(3) Manufacturer's name.

(4) Beyond-use date.

**§ 27.619. Production record.**

The pharmacist shall prepare and keep a production record for a minimum of 2 years for each drug product compounded. The record shall include the following information:

(1) Production date.

(2) List of ingredients and quantity of each ingredient used.

(3) Initials or other identifier of the person or persons involved in the compounding.

(4) Initials or other identifier of the pharmacist verifying the final compounded product.

(5) Internal control or prescription number and, if the prescription is filled using a product compounded in bulk, the internal control number assigned to the batch and recorded in the batch production record in accordance with § 27.623 (relating to production record for drugs compounded in bulk quantities).

**§ 27.620. Label information required.**

The label affixed to or on the dispensing container of any compounded drug product dispensed by a pharmacy pursuant to a prescription or drug order shall bear the information as required in § 27.18(d) (relating to standards of practice) and the following:

(1) The name of the compounded drug, and the strength, dosage form and quantity of the drug dispensed.

(2) Beyond-use date.

**§ 27.621. Compounding records.**

All 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 by § 27.18(b) (relating to standards of practice).

**BULK COMPOUNDING**

**§ 27.622. Master formula record.**

A pharmacist may compound drugs in bulk quantities for subsequent prescription labeling and dispensing in accordance with the provisions of § 27.604 (relating to dispensing compounded drugs). For each drug product compounded in bulk quantity, a master formula record containing the following information shall be prepared:

- (1) Name, strength and dosage form of the drug product compounded.
- (2) All components and an accurate statement of the weight or measure of each component.
- (3) Equipment needed to prepare the drug product.
- (4) Mixing instructions.
- (5) Beyond-use date.
- (6) Container, closures and packaging materials used in dispensing.
- (7) Storage requirements.
- (8) Labels and labeling with appropriate beyond use date and instructions for storage and use.

(9) Quality control procedures to include identification of the person or persons performing and directly supervising or checking each significant step in the compounding.

(10) Other factors pertinent to the replication of the drug product as compounded.

**§ 27.623. Production record for drugs compounded in bulk quantities.**

For each batch of drug product compounded, a production record containing the following information shall be prepared and maintained:

- (a) The information from the master formula record.
- (b) Records of each step in the compounding process including:
  - (i) Documentation of the name and strength of the compounded drug product.
  - (ii) Formulation record reference for the drug product.
  - (iii) Sources and lot numbers of the components.
  - (iv) Total number of dosage units compounded.
  - (v) Name of the person who prepared the drug product.
  - (vi) Name of the pharmacist who approved the drug product.
  - (vii) Date of preparation.
  - (viii) Prescription number or assigned internal identification number.
  - (ix) The results of quality control procedures as described in the pharmacy's continuous quality improvement program.
- (c) Beyond-use date.
- (d) Internal control number.

(e) Total yield.

**§ 27.624. Label information.**

For each batch of drug product compounded, labels containing the following information shall be prepared and affixed to each container:

(a) Drug product name or formula.

(b) Dosage form.

(c) Strength.

(d) Quantity per container.

(e) Internal control number.

(f) Beyond-use date.

\* \* \* \* \*



COMMONWEALTH OF PENNSYLVANIA  
DEPARTMENT OF STATE  
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS  
STATE BOARD OF PHARMACY  
Post Office Box 2649  
Harrisburg, Pennsylvania 17105-2649  
(717) 783-7156

March 1, 2017

The Honorable George D. Bedwick, Chairman  
INDEPENDENT REGULATORY REVIEW COMMISSION  
14<sup>th</sup> Floor, Harristown 2, 333 Market Street  
Harrisburg, Pennsylvania 17101

Re: Proposed Regulation  
State Board of Pharmacy  
16A-5419: Compounding

Dear Chairman Bedwick:

Enclosed is a copy of a proposed rulemaking package of the State Board of Pharmacy pertaining to Compounding.

The Board will be pleased to provide whatever information the Commission may require during the course of its review of the rulemaking.

Sincerely,

  
Janet Getzey Hart, Chairperson  
State Board of Pharmacy

JGH/KEM:jlt

Enclosure

cc: Ian J. Harlow, Commissioner of  
Professional and Occupational Affairs  
Leigh Chapman, Director of Policy, Department of State  
Timothy Gates, Chief Counsel  
Department of State  
Cynthia Montgomery, Regulatory Counsel  
Department of State  
Kerry E. Maloney, Counsel  
State Board of Pharmacy  
State Board of Pharmacy

