

**INFORMATION RELATED TO USP’s LACK OF AUTHORITY TO ESTABLISH  
“OFFICIAL” PROFESSIONAL PRACTICE STANDARDS FOR PHARMACY,  
MEDICINE AND NURSING**

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## I. USP AND PROFESSIONAL PRACTICE STANDARDS

### COMPOUNDINGTODAY.COM NEWSLETTER

July 29, 2016 Volume 13 Issue 30

Letter from the Editor

#### **Editorial: USP and Professional Practice Standards, A Follow-up**

Following a teleconference with USP staff and attorneys, I received a letter dated July 6, 2016 from USP presenting their reasons for believing the USP professional practice standards related to compounding are “**authoritative**”. (USP statements are in regular typeface and this Editors responses are in boldface.)

- 1. USP is a science-based nonprofit organization that sets forth public quality standards for medicines.
- **True, it is a science-based nonprofit organizations that sets forth public quality standards for medicines, but not for health professionals (pharmacists, physicians, nurses, etc.). Many aspects of the professional practice standards (<795>, <797>, <800> are not based on science so they are not appropriate to be included in the USP/NF.**
- 2. USP derives its authority to set standards from the USP Convention which is composed of delegates representing the profession of pharmacy, medicine, nursing and industry. The commitment to ensure public quality standards related to compounding has been reaffirmed a number of times in resolutions passed by the Convention.
- **USP states that it derives its “authority” from itself (the USP Convention). I don’t believe a private organization can give itself legal authority to establish “legal or authoritative” professional practice standards; this is the responsibility of the State Boards of Pharmacy.**
- 3. USP standards, general chapters and monographs-contained in the USP and NF have long been recognized in various provisions of the Federal Food, Drug and Cosmetic Act (FDCA).
- **True, but for compounding, they have been recognized as standards for ingredients and products/preparations only, not as professional practice standards.**
- 4. USP General Chapters are developed by Expert Committees which are composed of experts in the field. These standards are based on evidence when they are available, and based on best practices determined by the expertise of the Expert Committee with input from stakeholders through the public comment process.

- **USP Expert Committees are generally composed of those who volunteer and are not always necessarily expert in content but may have positions that contribute to their selection. In decades of service on national committees, it is apparent to me that committees are not always representative of the universe the committee is supposed to represent. As we know that “One size does not fit all”, “One committee does not represent all”. Consequently, there are many practices and areas that are not represented but patients and pharmacists suffer the fallout from lack of representation and standards not based on science and scientific studies.**
- **“Evidence and best practices” does not necessarily fit the requirement of item number one above, where “USP is a science-based...”. Best practices are not necessarily scientific and are fluid in nature; however, the resulting standards are applied to ALL as law in some states.**
- 5. USP standards for compounding were recognized in the 1997 Food Drug Administration Modernization Act in Section 503A which states that a compounder must use bulk drug substances and ingredients 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.” More recently, Congress enacted the 2013 Drug Quality and Security Act (DQSA) to clarify FDA’s authority over drug compounding and reaffirmed USP’s role under Section 503A. FDA’s current thinking is set forth in a published Guidance document which specifically references General Chapter <795> and <797>.
- **FDA has misrepresented Section 503A as previously discussed. The reference to USP is only to the standards for ingredients that must be used as described in the USP <795> section on “Component Selection, Handling, and Storage”, not to the entire chapter.**
- 6. USP and NF are recognized in state and federal laws and are enforced by regulatory authorities such as FDA and state boards of pharmacy.
- **USP standards are required for manufacturers but the use of USP compounding chapters by individual State Boards of Pharmacy varies from state to state.**
- 7. USP Chapters <795>, <797>, and <800> have been adopted and recognized by regulatory bodies such as FDA and states boards of pharmacy.
- **The chapters have not been adopted by all the State Boards of Pharmacy.**

## **2. PRESCRIPTION (EDITORIAL)**



## *Is the United States Pharmacopeial Convention, Inc. Authorized to Establish “Official” Practice Standards for Pharmacy, Medicine, and Nursing?*



The question has been brought up related to the authority of the United States Pharmacopeial Convention, Inc. (USP) to establish “official” practice standards for pharmacy and other professions (medicine, nursing), as in *United States Pharmacopeial (USP) Chapters <795>, <797>, <800>*, and others. Where did the USP obtain the authority to establish practice standards? To respond to this, we will look at this from the standpoint of the USP mission, Federal laws related to the USP, and the General Chapters contained in the *USP*. This information has been presented over the *CompoundingToday.com* weekly newsletters during the months of April, May, and June 2016 and will be presented in a future article in the *International Journal of Pharmaceutical Compounding*.

So far the following has been presented:

- USP standards **must be science-based**.
- *USP* professional practice standards chapters are **based predominantly on “Opinion” rather than on “Science” and “Scientific studies.”**
- The purpose of the *USP* General Chapters is to **centralize information** relevant to several **substance and product monographs**.
- The *USP* is recognized as **official** for its **standards for substances and products/preparations**.
- FDAMA97 and DQSA recognize the **USP standards for ingredients** used in compounding.
- There **appears to be no recognition** in the 1906 Federal Food and Drugs Act, FDAMA97, or DQSA concerning the USP developing professional practice standards for pharmacy, medicine, nursing, etc.
- *USP* Chapters <795>, <797>, <800>, and others were simply “inserted” into the *USP* in an inappropriate place, as they are not congressionally recognized as official or designed to be in the *USP*.

### **Authority for Establishing Professional Practice Standards**

The USP does not appear to have been granted the authority for establishing “OFFICIAL” professional practice standards for pharmacy, medicine, nursing, etc. The actual authority for establishing professional practice standards generally resides with the individual states, especially the state boards of pharmacy, medicine, nursing, etc. The individual Boards can either prepare the standards, use model standards from other sources (e.g., NABP in the case of pharmacy), or some other entity, etc. In summary, to view the USP professional practice standards published as “official” and “enforceable” does not seem to be appropriate and seems to be without foundation.

I recall back when we wrote the first practice standards at the request of the CEO of USP, Dr. Roger Williams; he explained that he wanted to establish a series of professional practice standards for the *USP*, including those for nonsterile compounding, sterile compounding, hazardous drugs compounding, etc. After the Pharmacy Compounding Expert Committee wrote *USP <795>*, the question of “where do we put it in the *USP*?” was asked. The chapters didn’t really “fit” anywhere, but it was decided by USP personnel to insert them in the Physical Tests section of the General Chapters. This was followed by *USP <797>*, etc.

At the time, the expert committee was given a task by the USP CEO and didn’t really consider the question of the authority to do this task. There was a lot of pressure from the FDA, and it was discussed at that time that these chapters may aid in keeping the FDA at bay...but we know that has not been the case.

In summary, it does not seem that there was ever any “legal recognition” provided to the USP to establish “official” professional practice standards...it was simply done. If this is the case, they are not “official” and should be removed from the *USP*, and the responsibility for development of professional practice standards be placed on the state boards of pharmacy.

**Lloyd V. Allen, Jr., PhD, RPh**

Editor-in-Chief of the *International Journal of Pharmaceutical Compounding and Remington: The Science and Practice of Pharmacy*, Twenty-second Edition

3. **CompoundingToday.com Newsletters: “Did you Know” and “Tip of the Week”**  
Loyd V. Allen, Jr., Ph.D., R.Ph.  
April 29, 2016 – June 3, 2016

## THE USP RULES AND PROCEDURES

CompoundingToday.com Newsletter April 29, 2016; Volume 13, Issue 17

### Did You Know

Under the **Rules and Procedures of the Mission and Preface** of the *USP*, the following is the first sentence under Governing Documents:

**USP-NF standards are recognized widely because they are authoritative and science-based and are established by a transparent and credible process.**

### Tip of the Week

The underlying criteria for standards in the USP-NF is that they are **SCIENCE-BASED**. If not, they should NOT be in the USP-NF. Take time and read through this section of the USP.

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## USP MISSION AND PREFACE

CompoundingToday.com Newsletter May 6, 2016; Volume 13, Issue 18

### Did You Know

USP Mission and Preface:

“A USP-NF monograph for an official substance, product, or preparation may consist of various components, including the article’s name; definition; packaging, storage, and other requirements; and a specification. **General chapters** provide frequently cited procedures, sometimes with acceptance criteria, in order to compile into one location repetitive information that is applicable to many monographs.

### Tip of the Week

The USP-NF contains official substance (ingredient) and product monographs for official articles recognized in USP-NF. With few exceptions, all articles for which monographs are provided in USP-NF are legally marketed in the United States or are contained in legally marketed articles. **USP-NF also includes official monographs for compounded preparations.**

**(Editor’s Note: A brief review of the development of **General Chapters** follows.)**

USP 1            1820    NO GENERAL CHAPTERS

USP 18          1970    NO GENERAL CHAPTERS (Just sections)

General Tests, Processes, and Apparatus

(The purpose was to centralize information relevant to several monographs in one place so it would not have to be duplicated in

the book numerous times with each monograph. No numbering system used).

USP 19	1975	GENERAL CHAPTERS (Format introduced for the first time) General Tests and Assays General Information, Processes, Techniques, and Apparatus (No numbering system used).
USP 20	1980	GENERAL CHAPTERS (Numbering system introduced) General Tests and Assays (1-999) General Information (1000-1999)
USP 39	2016	GENERAL CHAPTERS General Tests and Assays (1-999) General Information (1000-1999) Dietary Supplements (2000-2999)

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## FEDERAL LAW

CompoundingToday.com Newsletter May 13, 2016; Volume 13, Issue 19

### Did You Know

The **1906 Federal Food and Drugs Act** was the first to recognize the USP and NF as official compendia. The Act states the following under Definitions:

“That the term “drug,” as used in this act, shall include all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substance of mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or animals.”

It goes on in Section 7 “Adulterations” to state that **when a drug is sold under or by a name recognized in the USP or NF, it is required to meet the USP or NF standards unless it is so labeled. Otherwise, it is “adulterated”.**

### Tip of the Week

This is the original law that provided the USP and NF with legal recognition for enforceable standards related to adulteration, misbranding etc. **It relates to standards for the ingredients and products.**

### So far we know that:

1. USP standards must be **science-based**.
2. USP General Chapters are to **centralize information** relevant to several substance and product monographs.
3. The USP is recognized as official because of its **standards for substances and products**.

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## FEDERAL LAW

CompoundingToday.com Newsletter May 20, 2016; Volume 13, Issue 20

### Did You Know

**The Food and Drug Administration Modernization Act of 1997: FDAMA 97**, as it relates to the USP or NF states the following:

“(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-

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:...

(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:...**

### Tip of the Week

FDAMA 97 and the USP relates to the “ingredients” that are to be used in compounding. The reference to the USP chapter on pharmacy compounding relates to the section on “Component Selection, Handling, and Storage” that details the “guidelines” that shall be followed when selecting, handling and storing components for compounded preparations. Again, it relates to **“ingredients”**.

### So far we know that:

1. USP standards must be **science-based**.
2. USP General Chapters are to **centralize information** relevant to several substance and product monographs.
3. The USP is recognized as official because of its **standards for substances and products**.
4. FDAMA97 recognizes the USP **standards for ingredients** used in compounding.

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## FEDERAL LAW

CompoundingToday.com Newsletter May 27, 2016; Volume 13, Issue 21

### Did You Know

**The Drug Quality and Security Act,” H.R. 3204, DQSA**, refers to the USP as follows:

(2) **BULK DRUG SUBSTANCES**- The drug is compounded in an outsourcing facility that does not compound using **bulk drug substances** (as defined in section 207.3(a)(4) of title 21, Code of Federal Regulations (or any successor regulation)), unless-

(B) if an applicable monograph exists under the United States Pharmacopeia, the National Formulary, or another compendium or pharmacopeia recognized by the Secretary for purposes of this paragraph, the bulk drug substances each comply with the monograph;

(D) (3) **Ingredients** (Other than bulk drug substances).-If any **ingredients** (other than bulk drug substances) are used in compounding the drug, such **ingredients** comply with the standards of the applicable United States Pharmacopeia or National Formulary monograph, if such monograph exists, or of another compendium or pharmacopeia recognized by the Secretary for purpose of this paragraph if any.

### Tip of the Week

Similar to last week's discussion, both FDAMA97 and the DQSA refer to the USP-NF as it relates to the quality of **"ingredients"** used in compounding.

### So far we know that:

1. USP standards must be **science-based**.
2. USP General Chapters are to **centralize testing information** relevant to several substance and product monographs.
3. The USP is recognized as official because of its **standards for substances (ingredients) and products/preparations**.
4. FDAMA97 recognizes the USP standards for **ingredients** to be used in compounding.
5. DQSA recognizes the USP standards for **ingredients** to be used in compounding.
6. There is nothing in the 1906 Act, FDAMA97 or DQSA concerning practice standards for pharmacy, medicine, nursing, etc.

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### USP GENERAL CHAPTERS-CHAPTERS THAT DO NOT "FIT"

CompoundingToday.com June 3, 2016; Volume 13, Issue 22

### Did You Know

...that USP Chapters <795> and <797> and <800> are located in the "Physical Tests and Determinations" section of the General Chapters sandwiched in between the following general chapters, as follows:

...

<790> **Visible Particulates in Injections**

<791> **pH**

<795> **Pharmaceutical Compounding-Nonsterile Preparations**

<797> **Pharmaceutical Compounding-Sterile Preparations**

<800> **Hazardous Drugs-Handling in Healthcare Settings**

<801> **Polarography**

<811> **Powder Fineness**

...

Do they really belong here? Just a reminder, the purpose of the General Chapters is to centralize information relevant to several substance and product monographs.

### Tip of the Week

It is quite evident that Chapters <795>, <797>, <800>, setting professional practice standards for pharmacy, medicine and nursing, were not intended to be “Physical Tests and Determinations”, as they do not “centralize information relevant to several substance and product monographs.

### So far we know that:

1. USP standards must be **science-based**.
2. USP General Chapters are to **centralize information** relevant to several substance and product monographs.
3. The USP is recognized as official because of its **standards for substances and products/preparations**.
4. FDAMA97 recognizes the USP standards for **ingredients** used in compounding.
5. DQSA recognizes the USP standards for **ingredients** used in compounding.
6. There appears to be no authorization in the 1906 Act, FDAMA97 or DQSA concerning the USP developing professional practice standards for pharmacy, medicine, nursing, etc.
7. USP Chapters <795>, <797>, <800> and others were simply “inserted” into the USP in an inappropriate place as they are not congressionally authorized or designed to be in the USP.

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#### 4. SECTION 503a REFERS ONLY TO “INGREDIENTS/BULK DRUG SUBSTANCES” IN THE USP

##### Section 503A of the Federal Food, Drug, and Cosmetic Act

Please note: Section 503A has been amended by the Compounding Quality Act, as described in [Section 106\(a\)](#)<sup>1</sup> of the Act, and these amendments are not reflected in the text below.

<<NOTE: 21 USC 353a.>> ``SEC. 503A. PHARMACY COMPOUNDING.

``(a) In General.--Sections 501(a)(2)(B), 502(f)(1), and 505 shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the unsolicited 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) 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 [[Page 111 STAT. 2329]]

“(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 (d);

“(ii) that are manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); 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. [[Page 111 STAT. 2330]]

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) Advertising and Promotion.--A drug may be compounded under subsection (a) only if the pharmacy, licensed pharmacist, or licensed physician does not advertise or promote the compounding of any particular drug, class of drug, or type of drug. The pharmacy, licensed pharmacist, or licensed physician may advertise and promote the compounding service provided by the licensed pharmacist or licensed physician.

“(d) 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), 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) 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.

“(e) Application.--This section shall not apply to--“(1) compounded positron emission tomography drugs as defined in section 201(ii); or“(2) radiopharmaceuticals.

“(f) Definition.--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.”.

<<NOTE: 21 USC 353a note.>> (b) Effective Date.--Section 503A of the Federal Food, Drug, and Cosmetic Act, added by subsection (a), shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act.

## 5. UNITED STATES PHARMACOPEIA 39-NATIONAL FORMULARY 34, 2016

### USP General Chapter <795> Pharmaceutical Compounding-Nonsterile Preparations

#### **Component Selection, Handling and Storage**

“The following guidelines shall be followed when selecting, handling, and storing components for compounded preparations.”

*Note: This section of USP Chapter <795> goes on to describe 11 guidelines for the selection, handling and storage of **components/ingredients/bulk substances** used in compounded preparations. This section of USP <795> is what is referred to in the law.*

6. FDA MIS-STATES THE FFDCA IN ITS CPG



## Discrepancies in the Law and the U.S. Food and Drug Administration Pharmacy Compounding Compliance Policy Guidelines

Loyd V. Allen, Jr., PhD, RPh

The following are some excerpts from (1) the Compliance Policy Guidelines (CPG) dated June 2016, Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act), Revision 2, and (2) Section 503A of the FD&C Act, and some comments. Emphasis has been added by the author.

### THE COMPLIANCE POLICY GUIDELINES (EXCERPTS)

- This guidance issued in the process of implementing DQSA 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.
- 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. **(Editor's Note: It requires violation of the "Act" and not of the "CPG."**
- In general, FDA's guidance documents state that they 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.
- 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:

- section 501(a)(2)(B) (concerning current good manufacturing practice);
- section 502(f)(1) (concerning the labeling of drugs with adequate directions for use); and
- section 505 (concerning the approval of drugs under new drug applications [NDAs] or abbreviated new drug applications [ANDAs]).

• 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:

- 3. The drug product is compounded in compliance with the *United States Pharmacopoeia (USP) chapters* on pharmacy compounding 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. **(Editor's Note: Item 3 in the CPG immediately above has been reworded by the FDA and now means something different than what is currently in the 503A law.)**

### THE 503A LAW

The law states:

"(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 *USP* or *NF* monograph, if a monograph exists, and the *USP* chapter on pharmacy compounding;

AND LATER SAYS:

"(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;"

### DISCREPANCIES

Both of the instances in the law are referring to "ingredients" to be used in pharmacy compounding. **Only a single chapter is referred to in the law.** The law is referring to the *USP* <795> section on "Component Selection, Handling, and Storage." The law refers to "the *USP* chapter on pharmacy compounding" in both cases, whereas the CPG refers to "...chapters on pharmacy compounding." Again, another difference as to the original intent and the current wording of the law is to a single *USP* <795> chapter on compounding. **(Note: *USP* <797> was not in existence at the time of enactment of the Food and Drug Administration Modernization Act of 1997 (Public Law 105-115) (the Modernization Act).)**

At issue here is the way the CPG has been reworded to make it apply to multiple chapters, not just to the section on "ingredients that can be used in compounding described in the chapter" in *USP* <795>.

It appears there is a discrepancy between the Law and the FDA CPG. Another discrepancy involves the clear wording that a CPG is not enforceable but the FDA does enforce the CPGs.

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## 7. SUMMARY OF THE ISSUES

- The USP has never been granted the authority to develop professional practice standards for pharmacy, medicine and nursing.
- 
- The USP professional practice standards are too often based on opinions and not science; if not all science-based, they do not belong in the USP.
- 
- Professional Practice Standards should be removed as “official/authoritative/enforceable” from the USP.
- 
- The responsibility for laws, regulations and practice standards for pharmacy lies with the individual State Boards of Pharmacy.
- 
- Will there even be a need for additional Practice Standards in the future? Possibly so; we already have those for nonsterile and sterile compounding and for compounding with hazardous drugs that each state board can modify for their specific states.
- 
- If new standards are needed, they can be developed by the individual state boards of pharmacy and shared.
- 
- Many local and state issues may dictate different standards, not “one size fits all”.

Compiled on September 1, 2016.  
Lloyd V. Allen, Jr., Ph.D., R.Ph.