Date: Monday, October 20, 2014
Time: 8:00 am – 9:30 am
Location: Austin Convention Center, Room 17AB, Level 4

Title: Compounding - Important Developments That Will Affect Your Practice
ACPE # 207-000-14-223-L03-P · 0.15 CEUs
ACPE # 207-000-14-223-L03-T

Activity Type: Application-based
Speaker: Gay Dodson, Executive Director, Texas State Board of Pharmacy
David Miller, Executive Vice President and CEO, IACP
Jeanne Sun, USP

Pharmacist and Pharmacy Technician Learning Objectives:
Upon completion of this activity, participants will be able to:
1. Summarize developments in the implementation of Drug Quality and Safety Act (DQSA).
2. Discuss FDA’s actions on the newly created outsourcing facility classification.
3. Explain the provisions in USP General Chapter <800> and its implications for community practice compounders.

Disclosures:
Gay Dodson declares no conflicts of interest or financial interest in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

David Miller declares no conflicts of interest or financial interest in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

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Compounding
Important Regulatory and Legislative Developments That Will Affect Your Practice

Disclosure
David Miller declares no conflicts of interest or financial interest in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

Learning Objectives
At the conclusion of this program, the pharmacist or pharmacy technician attendee will be able to:
- Compare and contrast the components of the Drug Quality and Security Act of 2013 with previous federal requirements.
- Identify four specific areas in which federal and state compounding laws differ or appear to be in conflict.
- Describe three federal legislation actions occurring in the next year that will affect compounding pharmacy practice.
- List three resources for staying current on changing regulatory and legislative issues.
• 2012 – NECC Tragedy
• 2013 – Congressional Response
  – The Drug Quality & Security Act
• 2014 – FDA begins implementation of DQSA
• 2015 – Ongoing implementation, possible “technical corrections” to the bill
• 2016 – Practice adjusts/life goes on

HR 3204 - DQSA
• The Drug Quality and Security Act
  – Enacted 27 November 2013
  – Not S. 959… Not HR 3089…
• Three Sections
  – Reaffirmation of FDCA 503A with changes
  – Addition of new FDCA 503B – outsourcing facilities
  – National track-and-trace system for distributors and manufacturers

The Compounding Stuff
• The Drug Quality and Security Act – HR 3204
  – Enacted 27 November 2013
  – Not S. 959… Not HR 3089…
• Three Two Sections
  – Reaffirmation of FDCA 503A with changes
  – Addition of new FDCA 503B – outsourcing facilities
  – National track-and-trace system for distributors and manufacturers
Not Just Pharmacists

- Section 503A of the FDCA (21 USC 353a)
  - Applies to all licensed physicians and pharmacists who are:
    - Engaged in compounding anywhere, any time
    - Compound for individual patients based upon a valid prescription
  - In order to be exempted from requirements for:
    - cGMPs - FDCA 501(a)(2)(B)
    - FDA approved labeling – FDCA 502(f)(1)
    - Submitting a new drug application – FDCA 505

FDCA Section 503A

- Let's Review
  - Bulk Ingredients
  - "Do Not Compound" Drugs
  - The MOU Limits
  - State Reporting to FDA
- Ask Yourself
  - What's Changed or New?
  - Where Are We Now?
  - What's Happening Next?

What's in 503A?

Bulk Ingredients May Be Used to Compound

- APIs must have a USP/NF monograph or
- Are components of an FDA approved drug or
- Appear on a list approved by the Secretary of HHS (delegates to the FDA) and
- Is from an FDA registered supplier and
- Has a valid certificate of analysis
- This is not new!!!
Regulatory Implementation

Bulk Ingredients
- FDA has asked for lists of APIs that are non-USP/non-FDA approved (Deadline: 4 March 2014, New Deadline: 30 September 2014)
  - They will be reviewed by the Pharmacy Compounding Advisory Committee (Nominations submitted on 14 March 2014)
  - Subsequently reviewed and approved by the FDA
  - Eventually published
- **Still unknown.** How will FDA handle…?
  - Compounding of homeopathic products, naturopathic products, dietary supplements, OTCs

API Drug Lists
- It is not out yet. The process started all over again.
- The PCAC has to review every submission.
- There is no appointed PCAC yet.
- There are **no “exemptions”**.

What’s in 503A?
**There Are Some Things You Can’t Compound**
- Drugs removed from the market for safety and efficacy reasons
- “Demonstrably Difficult” drugs
- Commercially available products
Regulatory Implementation

“Do Not Compound” Lists
• Drugs withdrawn from the market
• 25 new added to the list
• Deadline for comments was 2 September.
• When published, you will have to comply.

Regulatory Implementation

“Do Not Compound” Lists
• FDA has asked for lists of “demonstrably difficulty” drug products (Deadline: 4 March 2014)
  – They will be reviewed by the Pharmacy Compounding Advisory Committee (Doesn’t exist yet)
  – The lists do not yet exist

What’s in 503A?

There Are Some Things You Can’t Compound
• Drug Products that are “commercially available”
  – Essentially copies of a commercially available drug product except for when
  – A change is made for an “identified individual patient which produces a significant difference… between the compounded drug and the commercial product”
• This is not new!!!
Regulatory Implementation

“Do Not Compound” Lists – Commercially Available
- Applies only to individual patient prescriptions
  - FDA monitoring marketing, promotion, websites, Facebook postings, etc.
- Still unknown…
  - How will this be enforced? Who is responsible for maintaining documentation of a “significant difference” in the patient’s therapy.
  - Repackaging (e.g., Avastin®), compounding of certain commercial products paid or required by third-party payers (e.g., Makena®)

What’s in 503A?
The “Memorandum of Understanding”
- An agreement between a state and the FDA
  - addresses the distribution of inordinate amounts of compounded drug products interstate
  - provides for appropriate investigation by a State agency of complaints
- If no MOU exists, then the “default” limits
  - Interstate distribution of compounds to no more than 5 percent of the total prescription orders dispensed or distributed
- This is not new!!!

Regulatory Implementation
The MOU
- FDA is developing a template/model MOU with NABP
  - The draft MOU will be published for public comment
  - FDA intends to begin enforcement 90 days after distribution
- But…
  - Individual states have to follow their own hearing and publication rules
  - Board of Pharmacy comment periods
- Still unknown.
  - MOU with a Board of Pharmacy doesn’t apply to physicians
  - Is dispensing a patient prescription considered distribution?
  - What happens if the FDA and state can’t agree?
The MOU

- IT DOES NOT EXIST YET
- NOBODY HAS SEEN IT
- Hearing and comment process
- Default clause is 5%... Not 5% in the MOU
- Distribute ≠ Dispense ≠ Deliver

What's in 503A?

State Reporting to the FDA
- State Boards will be “required” to report
  - Disciplinary actions taken against a pharmacy for compounding violations
  - Disciplinary actions taken against a compounding pharmacy for violations
  - May prompt an FDA inspection/determination of 503A violations
- This is new!!!

* May be a mandatory component of the MOU but also is part of a whole new section in the law.

Change in Communication!

State Reporting to the FDA
- A direct outcome of the NECC/FDA/Mass Board of Pharmacy bungle
  - Will this be before, after or during a state investigation/disciplinary hearing?
  - What happens if there is an appeal of a notice of violation?
State Reporting to the FDA

- Assume that any compounding violation will precipitate an FDA action
- Still unknown…
  - Nothing requires a Board of Medicine… or nursing, dentistry, podiatry, etc. to report compounding violations of physicians

Speaking of States

- 2012 – NECC Tragedy
- 2013 – 64 state pieces of legislation (26 passed)
- 2014 – 79 pieces of state legislation (20 passed)
- 2015 – Focus on oversight and inspections, confusion with state v. federal authority
- 2016 – Practice adjusts/life goes on

State Legislative Focus

- Requiring out-of-state pharmacies to have a permit
  - Special permits for sterile compounding
- Additional inspections by Boards of Pharmacy
  - Funding for expanded staff and inspectors
- Mandatory compliance with USP standards for <795>/non-sterile and <797>/sterile
- Not a peep about physicians, nurses, dentists…
Compounding
The State Perspective
Gay Dodson, R.Ph.
Executive Director/Secretary

Disclosure
Gay Dodson declares no conflicts of interest or financial interest in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.

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Sterile Compounding

Fungal Meningitis Outbreak

- 2012 New England Compounding Center (NECC) in Framingham, MA.
- The Numbers:
  - 20 states had reported cases.
  - 751 cases of fungal infections.
  - 64 deaths.

Immediate Questions

- How many Texas licensed pharmacies compound high risk products?
- What’s the state of sterile compounding in Texas?
- Do we need to make changes in Laws and Rules?
How Many? – The Numbers

<table>
<thead>
<tr>
<th># Pharmacies Located in Texas</th>
<th># Pharmacies Located Out-of-State</th>
<th>Total</th>
</tr>
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<tbody>
<tr>
<td># Pharmacies that Compound Sterile Products</td>
<td>684</td>
<td>221</td>
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<tr>
<td># Pharmacies that Compound Low Risk Products</td>
<td>525</td>
<td>173</td>
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<tr>
<td># Pharmacies that Compound Medium Risk Products</td>
<td>442</td>
<td>155</td>
</tr>
<tr>
<td># Pharmacies that Compound High Risk Products</td>
<td>114</td>
<td>127</td>
</tr>
</tbody>
</table>

State of Practice? – Inspections

- Inspection Priorities
  - Pharmacies that:
    - Compound High Risk Preparations.
    - Have had previous non-compliance problems during inspections.
    - Compound Low and Medium Risk Preparations.

State of Practice? Early Inspection Experiences

- Most pharmacies were substantially in compliance with rules.
- 2-pharmacies were ordered to cease compounding of High-Risk preparations.
- Tools Available to TSBP “shut down” compounding operations:
  - Issuance of a “Warning Notice” with immediate due-date (voluntary compliance).
  - Summary Suspension of a license.
State of Practice? Testing of Compounded Products

### SUMMARY OF COMPOUNDED SAMPLE TESTING PROGRAM FY 2009 – FY 2013

<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>Total # Samples Tested</td>
<td>46</td>
<td>86</td>
<td>37</td>
<td>28</td>
<td>58</td>
<td>51</td>
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<tr>
<td># Non-Sterile Samples Tested</td>
<td>35</td>
<td>58</td>
<td>27</td>
<td>20</td>
<td>9</td>
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<tr>
<td># Potency Failures</td>
<td>6</td>
<td>13</td>
<td>4</td>
<td>2</td>
<td>1</td>
<td>5.2</td>
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<tr>
<td># Sterile Samples Tested</td>
<td>11</td>
<td>28</td>
<td>10</td>
<td>8</td>
<td>40</td>
<td>21.2</td>
</tr>
<tr>
<td># Sterility Failures</td>
<td>1</td>
<td>8</td>
<td>4</td>
<td>1</td>
<td>2</td>
<td>3.2</td>
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<td># Fungal Failures</td>
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<td>N/A</td>
<td>N/A</td>
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</tr>
<tr>
<td># Fungal Failures</td>
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<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>&lt;1</td>
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<tr>
<td># Fungal Failures*</td>
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<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
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</tr>
<tr>
<td># Endotoxin Failures</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

*Fungal Testing began in FY2013  **Nasal product

What do we need to change?

- The Board had established a task force to review and make recommendations for modifying the compounding regulations.
- New Regulations became effective on December 13, 2013.

2013 Texas Legislative Changes

- The Texas Pharmacy Act was amended to specify that:
  - New pharmacies that compound sterile preparations may not be licensed by TSBP until the pharmacy has:
    - been inspected to ensure the pharmacy meets the requirements of TSBP laws and rules; and
    - reimbursed the Board for all expenses incurred in inspecting the pharmacy, if the pharmacy is located in another state.
The Texas Pharmacy Act was amended to specify that:

- Existing pharmacies that compounding sterile preparations may not renew their registration unless the pharmacy has:
  - been inspected to ensure the pharmacy meets the requirements of TSBP laws and rules; and
  - reimbursed the Board for all expenses incurred in inspecting the pharmacy, if the pharmacy is located in another state.

- A pharmacy that compounds a sterile product must notify the Board:
  - Immediately of any adverse effects reported to the pharmacy or known by the pharmacy to be potentially attributable to a sterile product compounded by the pharmacy; and
  - Not later than 24-hours after the pharmacy issues a recall for a sterile product compounded by the pharmacy.

TSBP was given additional appropriations to:
- Hire 6 additional personnel directly related to the inspection pharmacies that compound sterile preparations; and
- Additional funding to test sterile preparations compounded by pharmacies.
Actions Since the 2013 Legislative Session

• New license designations were created for pharmacies that compound sterile products.
  – Class A-S (Community Pharmacy).
  – Class C-S (Institutional Pharmacy).
  – Class E-S (Non-Resident Pharmacy).

Actions Since the 2013 Legislative Session (cont.)

• A new inspection form was developed and is in use.
• TSBP has hired 5 new inspectors and 1 administrative person to assist with inspections.
• All inspectors received additional training for the inspecting of pharmacies that compound sterile preparations.

Federal Drug Quality and Security Act (DQSA)

• Signed into law on November 27, 2013.
• Title I – Compounding Quality Act.
  – Section 503A – Pharmacy Compounding.
  – Section 503B – Outsourcing Facilities.
Section 503A – Pharmacy Compounding

- Texas State Board of Pharmacy has clear jurisdiction over the regulation of pharmacies in Texas.

Section 503B – Outsourcing Facilities

- Texas law is not clear on who has jurisdiction over Outsourcing Facilities.
- Texas Department of State Health Services (DSHS) has the responsibility for the regulation of wholesalers, but the current law does not allow DSHS to create a category for Outsourcers.
- Currently TSBP and DSHS are cooperating in the regulation of these facilities.

2015 Texas Legislative Session

- Clarify who has authority over Outsourcers.
- Clarify the status of the Texas Law that allows pharmacies to compound for office use.
Questions?

Thank You!

USP Updates on Practitioner Related Standards

Jeanne Sun, PharmD
Associate Scientific Liaison
United States Pharmacopeial Convention
Disclosure

Jeanne Sun declares no conflicts of interest or financial interest in any product or service mentioned in this program, including grants, employment, gifts, stock holdings and honoraria.

Outline

• Overview of USP
• Compounding Overview
  – Expert Committee
  – Types of Standards
• Compounding General Chapters
  – Development and Revision Work

About USP

Scientific non-profit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements

USP's Mission:
To improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods.
About USP

What We Do Today
• Establish and disseminate public written standards for the quality, purity, identity, strength, and labeling of medicines
• Provide recommendations to practitioners on the safe use of medicines
• Work with international health agencies to improve the quality of medicines worldwide
• Educate practitioners, producers and others seeking information on quality and USP standards

About USP

- The United States Pharmacopeia National Formulary (USP-NF)
- Food Chemicals Codex (FCC)
- USP Dietary Supplements Compendium (DSC)
- USP Compounding Compendium
- Reference Standards
- USP Dictionary
- Other Resources
  - Pharmacopeial Forum (PF)
  - FCC Forum (FCCF)
  - Chromatographic Columns

Compounding Overview: Expert Committee and Standards
# 2010 – 2015 Compounding Expert Committee

- **Chair:** Gigi Davidson, R.Ph., DICVP, NC State University
- **Vice-Chair:** Lisa Ashworth, R.Ph., Children’s Medical Center Dallas

<table>
<thead>
<tr>
<th>Name</th>
<th>Institution/Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gus Bassani, Pharm.D</td>
<td>PCCA</td>
</tr>
<tr>
<td>Maria do Carmo Garcez, R.Ph.</td>
<td>ANIFARMAG – Brazil</td>
</tr>
<tr>
<td>Ed Elder, Ph.D.</td>
<td>University of Wisconsin</td>
</tr>
<tr>
<td>Deborah Houston, Pharm.D.</td>
<td>Advanced Home Care</td>
</tr>
<tr>
<td>Patti Kente, R.Ph., M.P.A</td>
<td>Cardinal Health</td>
</tr>
<tr>
<td>Keisha Lovoi, Pharm.D.</td>
<td>Woodlands Compounding Pharmacy</td>
</tr>
</tbody>
</table>

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# USP Standards

**General Notices**

- Provides the basic assumptions and definitions for applying USP-NF compendial standards, which are applied to official articles recognized in monographs and any applicable general chapters.

**General Chapters**

- Contain requirements applicable to monographs to which they apply.
  - General Chapter requirements supersede General Notice requirements in case of conflict.

**Monograph**

- Requirements are specific to the monograph in which they appear.
  - Monograph requirements supersede General Notice and General Chapter requirements in case of conflict.
General Chapters Overview

General Chapters can be:

- **Enforceable**
  - Numbered below <1000>

- **Informational**
  - Numbered above <1000>

- **Specific for dietary supplements**
  - Numbered above <2000>

- **Terminology**
  - “Shall” requirements
  - “Should” recommendations

Compounding General Chapters

- <795> Pharmaceutical Compounding – Nonsterile Preparations
- <797> Pharmaceutical Compounding-Sterile Preparations
- <1163> Quality Assurance in Pharmaceutical Compounding
- <1160> Pharmaceutical Calculations in Prescription Compounding
- <1176> Prescription Balances & Volumetric Apparatus

Compounding Monographs

- As of USP37-NF32 2S, there are 175 official compounding monographs published for human and veterinary use
- Includes dosage forms such as:
  - Oral Suspensions
  - Oral Solutions
  - Suppositories
  - Injections
  - Topicals
  - Ophthalmics
Compounding General Chapters: Development and Revision

USP <800>: Overview

<800> Hazardous Drugs – Handling in Healthcare Settings

- **New** proposed standard to protect personnel and environment when handling hazardous drugs (HDs)
- **Purpose:** To define processes intended to provide containment of hazardous drugs to as low as reasonably achievable

Chapter addresses:

- Standards that apply to all personnel who compound HDs preparations and all places where HDs are prepared, stored, transported, and administered
- Receiving, storing, compounding, dispensing, administering, and disposing of both nonsterile and sterile products and preparations

USP <800>: Existing References

- Chapter builds on the standards existing in compounding chapters
  - Adds in the elements of containment of HDs
- Existing references
  - OSHA Standards
  - NIOSH Alert
  - ASHP Guidelines on Handling Hazardous Drugs
  - ONS Publications
  - Incorporates principles of medication safety and worker protection
USP <800>: List of HDs

HD includes any drug identified by at least one of the following six criteria:
• Carcinogenicity
• Teratogenicity or developmental toxicity
• Reproductive toxicity in humans
• Organ toxicity at low doses in humans or animals
• Genotoxicity
• New drugs that mimic existing HDs

Chapter refers to NIOSH List

USP <800>: Scope

Chapter addresses, but is not limited to the:
• Receiving
• Storing
• Mixing
• Preparing
• Compounding (sterile and nonsterile)
• Dispensing
• Administering
• Disposing
• Manipulating (altering, counting, crushing, pouring)

Standards apply to all healthcare settings where HDs are prepared including:
• Pharmacies
• Hospitals
• Healthcare institutions
• Patient treatment clinics
• Physician’s practice facilities
• Veterinarians’ offices

• Receiving
  – To allow for safety in the receiving and internal transfer process
    • HDs should be received from the supplier sealed in impervious plastic to segregate them from other drugs
    • HDs should be immediately delivered to the C-SEC

• Storing
  – HDs shall be separate from storage of non-HDs
  – Storage of non-antineoplastic HDs shall be separate from storage of non-HDs
  – HDs shall not be handled in an area that is positive pressure relative to the surrounding areas.
USP <800>: Scope

Compounding
- Nonsterile
  - Require Containment Ventilated Enclosure
  - Negative pressure room with at least 12 ACPH
- Sterile
  - Require BSC or CACI in a negative pressure room with at least 12 ACPH
  - Eliminates low-volume of HDs exemption
  - Allows for an "unclassified" C-SCA

USP <800>: Scope

- Dispensing and Counting HDs
  - Dedicated equipment
  - No automated counting or filling machines
- Administration
  - Use Closed System Drug-Transfer Devices (CSTDs) when the dosage form allows
  - Wear Personal Protective Equipment (PPE)

USP <800>: Status

- March 28th, 2014
- June 12th, 2014
- July 31st, 2014
- August - Present

- Posted for Public Comment
- Public Comment Period Closed
- Open Microphone Session
- Review of all public comments submitted
USP <800>: Next Steps

Based on the nature and significance of the public comments:
- Forward
- Ballot
- Defer
- Cancel

Approve
- Not approve

Proposal re-published for public comment

USP <800>: Next Steps

- Subcommittee currently reviewing all public comments submitted.
  - Comments may be
    - Incorporated
    - Partially incorporated
    - Not incorporated
  - Comments will be addressed through commentary posted online (http://www.usp.org/usp-nf/official-text/proposal-status)

- Standards in USP-NF become official 6 months after publication
  - Delayed implementation

USP <797>: Intent to Revise

<797> Pharmaceutical Compounding – Sterile Preparations

- Purpose of Revision
  - To reflect new science, respond to stakeholder input, and improve the clarity of the general chapter.

- Current Progress
  - <797> Subcommittee began work in July 2010
  - <797> Expert Panel was formed in April 2013 for additional expertise
  - Collaborating with Microbiology Expert Committee on sterility assurance and testing
USP <795>: Revision Bulletin

<795> Pharmaceutical Compounding – Nonsterile Preparations

- Revision Bulletin
  - Posted November 22, 2013
  - Official January 1, 2014

<table>
<thead>
<tr>
<th>BUD by Type of Formulation</th>
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<tbody>
<tr>
<td>For Nonaqueous Formulations—The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.</td>
</tr>
<tr>
<td>For Water-Containing Oral Formulations—The BUD is not later than 14 days when stored at controlled cold temperatures.</td>
</tr>
<tr>
<td>For Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations—The BUD is not later than 30 days.</td>
</tr>
</tbody>
</table>

USP <1160>: Revision Proposal

<1160> Pharmaceutical Calculations in Pharmacy Practice

- Purpose
  - Change title to better describe contents of the chapter
  - To update the definitions, include more relevant calculations and problem examples, and add practical resources for practitioners

- Revisions proposed in PF 40(3) May/June 2014
  - Comment period ends July 31st, 2014
  - Targeted official publication in USP 38-NF 33 (1st Supplement)

- Available at:
  - https://www.usp.org/usp-nf/notices/GC1160-compounding-notice

USP <1176>: Revision Proposal

<1176> Balances and Volumetric Apparatus Used in Compounding

- Purpose
  - Change title to better describe contents of the chapter
  - To add information on mechanical and electronic balances, update information on use of graduates, and delete obsolete terminology

- Revisions to be proposed in PF 41(2) Mar/Apr 2015
- Comment period: Mar 2nd – May 31st, 2015
USP <1168>: New Development

• Purpose:
  - To provide additional standards for compounding for investigational preclinical and early phase I investigations
• New chapter proposal in PF39(5) Sept-Oct 2013
  - Public comment period closed Nov 30, 2013
  - Committee currently reviewing all public comments received