Healthcare Quality Standards
2015-2020 Work Plan

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Donna Bohannon is an employee of U.S. Pharmacopeial Convention (USP). The conflict of interest was resolved by peer review of the slide content. He declares no other conflicts of interest or financial interest in any product or service mentioned in this program, including grants, employment, gifts, stock holdings, and honoraria.
1. Provide an overview of the Healthcare Quality Standards Division
2. Describe new and revised USP standards
3. Explain USP Standards to the Digital Environment
Healthcare Quality Standards – Assessment Questions

1. What are the revisions to General Chapter <17>, Prescription Container Labeling?

2. What Expert Committees are within the Healthcare Quality Standards Division?

3. What is the resolution that guides the work of the Expert Committees within the Healthcare Quality Standards Division?

4. What are the 4 “buckets” of standard development that fuels the Healthcare Quality workplan?
USP 2015-2020 RESOLUTION 8

Explore Development of Quality Standards of Value to Practitioners and the Public

USP will collaborate with stakeholders to develop, strengthen, revise, and promote adoption of healthcare quality standards that address quality and safety related to the use of medications and that are of value to patients and practitioners.
2015–2020 Council of Experts

Expert Committees and Collaborative Groups

- Similar number of Expert Committees
- Retain Expert Panels in advisory capacity
- Joint Standards-Setting Subcommittees work across Expert Committees (reference standards, global standards, modernization…)

- Healthcare Quality Standards Collaborative Group
  - Nomenclature & Labeling
  - Compounding
  - Healthcare Quality

- Chemical Medicines Monographs Collaborative Group
  - Chemical Medicines Monographs 1
  - Chemical Medicines Monographs 2
  - Chemical Medicines Monographs 3

- Biologic and Biotechnology (B&B) Collaborative Group
  - B&B Peptides
  - B&B Proteins
  - B&B Complex Biologicals
  - B&B Biological Analysis

- Excipient Monographs Collaborative Group
  - Excipient Monographs 1
  - Excipient Monographs 2

- Dietary Supplements/Herbal Medicines/Foods Collaborative Group
  - Dietary Supplements
  - Herbal Medicines
  - Food Ingredients

- General Chapters Collaborative Group
  - Chemical Analysis
  - Physical Analysis
  - Statistics
  - Microbiology
  - Dosage Forms
  - Packaging and Distribution
Expert Committees (2015-2020)

- Compounding
- Nomenclature and Labeling
- Healthcare Quality
USP Standards: Ensuring Quality Medicine Reaches Every Patient
USP Standards: Ensuring Quality Medicine Reaches Every Patient

USP STANDARDS
- General Notices
- General Chapters
- Monographs and Reference Standards
USP Standards: Ensuring Quality Medicine Reaches Every Patient

USP STANDARDS
- General Chapters (e.g., Packaging and Distribution, Dosage Forms)
- Nomenclature and Labeling
USP Standards: Ensuring Quality Medicine Reaches Every Patient

USP HEALTHCARE QUALITY STANDARDS
- Nomenclature and Labeling
- Compounding – Sterile and Nonsterile
- Model Guidelines for Formularies
- Safe Medication Use
- Prescription Labeling
- Hazardous Drugs – Practitioner Handling

Suppliers

Manufacturers

Wholesale/Distributors

Pharmacies/Hospitals

Healthcare

Patients
USP Standards: Ensuring Quality Medicine Reaches Every Patient

SUPPLIERS

MANUFACTURERS

WHOLESALE/DISTRIBUTORS

PHARMACIES/Hospitals

Healthcare

Patients

USP HEALTHCARE QUALITY STANDARDS

- Nomenclature and Labeling
- Compounding – Sterile and Nonsterile
- Model Guidelines for Formularies
- Safe Medication Use
- Prescription Labeling
- Hazardous Drugs – Practitioner Handling

NATIONAL QUALITY STRATEGY

Better Care. Healthy People/Healthy Communities. Affordable Care.
Current public health issues are fueling the work of this group.
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  • Safe sterile compounding of medicines
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- Safe sterile compounding of medicines
- Increased focus on healthcare quality and health informatics
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- Increased globalization of drug nomenclature and associated chemical information
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- Safe sterile compounding of medicines
- Increased focus on healthcare quality and health informatics
- Increased globalization of drug nomenclature and associated chemical information
Biosimilar Naming - USP comments
Monograph System
Unintended Consequences
Formation of Joint Subcommittee – Biologics and Nomenclature to address Final rule
Current public health issues are fueling the work of this group

- Safe sterile compounding of medicines
- Increased focus on healthcare quality and health informatics
- Increased globalization of drug nomenclature and associated chemical information

USP healthcare quality standards are recognized in federal law and are increasingly adopted by other federal and state agencies
Current public health issues are fueling the work of this group

- Safe sterile compounding of medicines
- Increased focus on healthcare quality and health informatics
- Increased globalization of drug nomenclature and associated chemical information

USP healthcare quality standards are recognized in federal law and are increasingly adopted by other federal and state agencies

USP is being sought as a thought leader and key contributor to emerging opportunities
Healthcare Quality Standards
Expert Committee
Healthcare Quality Expert Committee Workplan

Classification
- Medical Model Guidelines
- Allergies and Intolerance
- Guidelines US marketed Products

Health Literacy
- Prescription Container labeling
- USP Pictograms
- After Visit Summary

Electronic Environments
- EHR
- Patient Portals
- Consumer Applications
- Parenteral Nutrition

Safety
- Emerging Issues
Section 1860D-4(b)(3)(C) defines role of USP:

“(ii) MODEL GUIDELINES- The [HHS] Secretary shall request the United States Pharmacopeia to develop, in consultation with pharmaceutical benefit managers and other interested parties, a list of categories and classes that may be used by prescription drug plans under this paragraph and to revise such classification from time to time to reflect changes in therapeutic uses of covered part D drugs and the additions of new covered part D drugs.”

Section 1860D-11(e)(2)(D) creates “safe harbor”:

“(ii) USE OF CATEGORIES AND CLASSES IN FORMULARIES.- The Secretary may not find that the design of categories and classes within a formulary violates clause (i) if such categories and classes are consistent with guidelines (if any) for such categories and classes established by the United States Pharmacopeia.”
Classification: USP Medicare Model Guidelines Development

USP MMG v1.0 (2005) involved:
- Expert Committee
- Environmental scan
- Public advisory meetings
- Public comment process

Revision from “time to time”:
- USP MMG v2.0 (2006)
- USP MMG v3.0 (2007)
- USP MMG v4.0 (2008)
- USP MMG v5.0 (2011)
- USP MMG v6.0 (2014)

Note:
USP Medicare Model Guidelines v6.0

Available on the USP website: [www.usp.org](http://www.usp.org)

February 4, 2014

<table>
<thead>
<tr>
<th>USP Category</th>
<th>USP Class</th>
<th>Change language</th>
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<tbody>
<tr>
<td>Analgesics</td>
<td>Nonsteroidal Anti-inflammatory Drugs</td>
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<td>Opioid Analgesics, Long-acting</td>
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<td>Opioid Analgesics, Short-acting</td>
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<td>Anesthetics</td>
<td>Local Anesthetics</td>
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<td>Anti-Addictive Substance Abuse Treatment Agents</td>
<td>Alcohol Deterrents/Anti-craving</td>
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<td>Opioid Dependence Treatments</td>
<td>Subatomic change for therapeutic of drug</td>
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<td>Opioid Antagonists</td>
<td>Subatomic change for therapeutic of drug</td>
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<td>Opioid Reversal Agents</td>
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<td>Smoking Cessation Agents</td>
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<td>Antibiotics</td>
<td>Aminoglycosides</td>
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<td>Beta-lactam, Cephalosporins</td>
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<td>Tetracyclines</td>
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<td>Antibiotics, Other</td>
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<td>Intradermal Anti-infectives</td>
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<td></td>
<td>Calcium Channel Modifying Agents</td>
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ACA requires health plans to cover “Essential Health Benefits” (EHB) within 10 benefit categories, including prescription drugs.

HHS Final Rule (Feb 25, 2013) cites USP Medicare Model Guidelines (MMG)

“...in order to comply with the requirement to cover EHB, a plan would cover at least the greater of:

(1) One drug in every USP category and class; or
(2) the same number of drugs in each category and class as the EHB-benchmark plan. “

For 2014-2015, HHS makes use of USP Medicare Model Guidelines v5.0
The purpose of this Expert Panel will be to create an initial set of classes of known drug cross-allergies and cross-intolerance, and to assign drug codes to support electronic health record (EHR) documentation.
Purpose
– To develop standards for prescription container labels as they are the patient’s best source. The prescription container label must be able to fulfill the professional obligations of the healthcare provider to give the patient all the information needed to understand how to safely use the medication

Official May 2013

Revision to be published February 2016
– Access for visually impaired
– Endorsement of the Universal Medication Schedule
– Endorsement of metric units and associated dosing components for oral liquids

1 in 5 Americans have access to a patient–centered label
At a minimum, a prescription container shall be labeled in a **patient-centered manner**. The label shall contain **essential information** that is important for the patient’s safe and effective use of the medicine. Labels should be designed and formatted to **improve readability and understanding**.

**Example of Prescription Container Labeling:**

- Adopt one standard warning label for all acetaminophen-containing prescription medicines.
  - Standardize prioritization of print sequence to print among the top three pharmacy warning labels.

- Always completely spell “acetaminophen” and all other active ingredients on the prescription label.
  - No abbreviation, acronym or truncated version of any active ingredient should be permitted on a prescription label.

![Example Label Image]
When **oral liquid dosage forms** are prescribed, the **appropriate dosing component** (e.g., oral syringe, dosing cup) shall **be provided** to the patient or caregiver to accurately measure and administer the oral medication. The graduations on the component shall be legible and indelible, and the associated **volume markings** shall be in **metric units** and limited to a single measurement scale that **corresponds with the dose instructions** on the prescription container label (see *Packaging and Storage Requirements* <659>).
“A Spoonful of Sugar makes the medicine go down”….no more

- The teaspoon definition has been removed from the USP-NF
- Public comments related to delayed implementation only
Standardized **graphic images** that help convey medication instructions, precautions, and/or warnings to patients and consumers.
- Deliver important information to patients with a lower level reading ability and patients for whom English is a second language.
- Reinforce printed or oral instructions.

Currently USP offers 81 pictograms
- Tested for comprehension

Available for download (free of charge)
Purpose

- To describe optimal physical environment standards to promote accurate medication use and improve performance since the work environment has been identified as one of the most commonly reported factors contributing to medication errors.

Physical Environments addressed:

- Illumination
- Sound and Noise
- Interruptions and Distractions
- Physical Design and Organization of Workspace
Electronic Environments that Promote Safe Medication Use

- Allergy and Intolerance Value sets
- Parenteral Nutrition Safety
- Electronic Health Record
  - Interoperability
  - Usability
General Chapter <7> Labeling

Single entity drug products that can also be expressed as a ratio such as epinephrine shall be labeled only in terms of strength per mL.

- Ratio expression such as 1:1000 is an unacceptable format for single entity drug products.

- **Official:** May 1, 2016
HQ EC Workplan Initiatives

- **Subcommittees**
  - Medicare Model Guidelines
  - Safety
  - IV Concentration Standardization

- **Expert Panels**
  - Allergy and Intolerances Value Sets
  - US marketed drug products
  - Health Literacy
  - Parenteral Nutrition
Thank You
1. a. Best practices for the visually impaired, b. Endorsement of the Universal Medication Schedule, c. Endorsement of the use of metric and associated components


3. Resolution 8 - USP will collaborate with stakeholders to develop, strengthen, revise, and promote adoption of healthcare quality standards that address quality and safety related to the use of medications and that are of value to patients and practitioners