



U.S. PHARMACOPEIA
The Standard of QualitySM

USP's Model Guidelines for the Medicare Drug Benefit

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MMA, Private Plans, and Competition:
Formulary Design - Balancing Cost and Access

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Topics

- ◆ USP Background
- ◆ USP's Role under the Medicare Modernization Act (MMA)
- ◆ Development of the Model Guidelines
- ◆ Model Guidelines Revision Process



USP: Who We Are

- ◆ Volunteer-driven, non-profit, non-governmental entity that has developed and disseminated authoritative standards and health care information since 1820
- ◆ Standards and information have been legally recognized and widely adopted
 - ▶ Objective, unbiased and science-based
 - ▶ Developed through credible, transparent process by nationally and internationally recognized scientists and practitioners with expertise in specific fields



USP: Who We Are





USP's Role in Drug Standards & Information

- ◆ USP-NF: “official compendia” of drug standards recognized under the Food, Drug, and Cosmetic Act, Social Security Act (SSA) and laws of many other countries
 - ▶ Strength, quality and purity standards
 - ▶ Packaging and labeling requirements
- ◆ USP-DI: recognized in SSA as authority for off-label use reimbursable under Medicare/Medicaid
- ◆ Responsible for developing VA formulary categories and classes from 1985-2004



USP's Role Under Medicare Modernization Act

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

“(ii) MODEL GUIDELINES- The 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.”



Development of Model Guidelines

- ◆ Developed by USP's Model Guidelines Expert Committee, with input from all stakeholders
- ◆ Final Model Guidelines
 - ▶ 41 Therapeutic Categories
 - ▶ 137 Pharmacologic Classes
- ◆ Formulary Key Drug Types (118)
 - ▶ In addition to classes/categories in which two drugs would be required, Expert Committee developed list of more specific "subgroups" from which at least one drug should be included to ensure comprehensiveness and non-discrimination
 - ▶ Incorporated by CMS in its formulary review guidance
 - Check for comprehensiveness
 - At least one drug required, unless justification provided
 - Applies to all formularies, regardless of classification system used



Value of USP's Work

- ◆ Benefits of Model Guidelines and FKDT
 - ▶ Model Guidelines provide formulary structure that will help assure beneficiary access while preserving needed flexibility for PBMs and plans
 - ▶ FKDT provide additional protection for beneficiaries and additional tool for CMS in reviewing formularies, without unduly burdening PBMs and plans
- ◆ While neither are mandatory, use of “standards” promotes consistency, fairness and ease of administration
- ◆ Unbiased, science-based drug information benefits CMS, PBMs and plans, practitioners and patients and helps achieve comprehensive yet affordable benefit



Revision Process

- ◆ New Model Guidelines Expert Committee, consisting of 2005-2010 Information Committee chairs elected by USP's Convention
- ◆ Determining appropriate revisions based on:
 - ▶ Information regarding new Part D drugs and new uses for existing Part D drugs
 - ▶ Comments and information received from third parties since submission of Model Guidelines
 - ▶ Comments received from CMS based on the formulary review process



Revision Timeline

- ◆ Early October: contract with CMS finalized
- ◆ Late October: Advisory Forum teleconferences
- ◆ Early December: post draft revisions to USP website for public comment
- ◆ Mid-December: meetings with Advisory Forums
- ◆ End of December: public comment period ends
- ◆ Early January: draft revisions to CMS
- ◆ End of January: final revisions due to CMS
- ◆ Check USP website for updates and additional information: **www.usp.org**



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Thank You