



U.S. Pharmacopeia
The Standard of Quality™

**2005–2010 Medicare Model Guidelines Expert Committee (MGEC)
Meeting #6
Tuesday, March 28, 2006
Snake River Lodge, Jackson Hole, WY**

Public Record of Meeting

Goals and Anticipated Outcomes

1. To review the Model Guidelines Phase II work
2. To discuss future activities of the Model Guidelines Expert Committee and the Information Expert Committees

Opening and Procedural Matters

After establishing that a quorum was present, the meeting was called to order and everyone was welcomed to the sixth meeting of the Model Guidelines Expert Committee for the 2005–2010 cycle.

The minutes of the previous meeting were reviewed. It was noted that the spelling of the word “ophthalmic” needed to be corrected. The minutes were unanimously approved with this correction.

Review of Model Guidelines Phase II Work

- The revised Model Guidelines (MGs) for the 2007 benefit year were completed and submitted on time to the Centers for Medicare and Medicaid Services (CMS) on February 6, 2006.
- The formulary designs of prescription drug plans that adopted the MGs were approved by CMS.
- Questions that the MGEC asked CMS are now included as Frequently Asked Questions on the CMS website.
- The current focus of CMS administrators is to enroll beneficiaries in the Medicare Part D program.
- USP is working with CMS and Congress to obtain a contract for the 2008 benefit year.

Discussion

- Use of the MGs by plans is not expected to decrease. Changes in the revised MGs should not inhibit implementation by the plans.
- There may be a misconception that Formulary Key Drug Types (FKDTs) which require one drug will not give plans flexibility. FKDTs are not mandatory, if the plan can show justification why inclusion is not necessary. Also, plans may offer more than one drug in a FKDT. Beneficiaries may appeal plan decisions not to cover specific drugs.
- The work of the MGEC was compressed into a few short months. Moving forward, the work will be ongoing throughout the year and will be accomplished with more input from the Information Expert Committees.

Model Guidelines Revision Process

- A preliminary draft of the MG Revision Process, developed by USP staff, was included in the briefing materials.
- The first two versions of the MGs were the result of work by the MGEC. The proposed new process would enable the Information Expert Committees to work on specific sections of the MGs and send their recommendations to the MGEC in the form of quarterly reports.
- Pharmaceutical manufacturers and other interested parties will have the opportunity to submit information on new FDA-approved drugs or revised FDA-approved indications to the Information Expert Committees for their consideration.
- The first step in the revision of the MGs would be to expand the drug listing table.
- The second step would be to expand or contract classes and FKDTs.
 - FKDTs or classes could be collapsed if no clinical distinction between classes or FKDTs could be demonstrated.

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- Three articles on noninferiority and equivalence were including in the briefing materials.

Discussion

- A scientific evidence base is needed.
- The Veteran's Administration (VA) has developed formularies. Collaboration with the VA could be useful.
- There are thirteen Evidence-based Practice Centers (EPCs) in the United States. The following list was obtained from the Agency for Healthcare Research and Quality (AHRQ) website (<http://www.ahcpr.gov/clinic/epc/epcenters.htm>):
 - Blue Cross and Blue Shield Association
 - Duke University
 - ECRI
 - Johns Hopkins University
 - McMaster University
 - Oregon Health & Science University
 - RTI International—University of North Carolina at Chapel Hill
 - Southern California Evidence-based Practice Center—RAND
 - Stanford University, Stanford, and University of California
 - Tufts-New England Medical Center
 - University of Alberta
 - University of Minnesota
 - University of Ottawa
- The FDA is interested in safety when comparing different drugs and is considering the issue of therapeutic equivalence versus pharmacologic equivalence.

Adjournment

The attendees were thanked for a productive meeting. The meeting was adjourned at 7:35 p.m.

