



U.S. Pharmacopeia  
The Standard of Quality™

**2005–2010 Model Guidelines Expert Committee (MGEC)  
Meeting #10  
Tuesday, April 17, 2007  
Fire Sky Resort and Spa  
Scottsdale, Arizona**

**Expert Committee Meeting Summary**

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**Goals and Anticipated Outcomes**

- Review and discussion of Model Guidelines Version 3.0
- Review of the contract with the Centers for Medicare and Medicaid Services (CMS)
- Review of the workplan for creation of Model Guidelines Version 4.0
- Review and discussion of *Annals of Internal Medicine* issues

**Opening and Procedural Matters**

**Welcome, Call Meeting to Order**

After determining that a quorum was present, the meeting was called to order.

**Approval of Minutes of the Previous Meeting**

The minutes of the last meeting, held on January 9, 2007, were previously approved via e-mail ballot. A redacted version of the minutes is available on the USP website.

**Potential Future Drug Information Activities**

- With the expiration of the Thomson agreement and the noncompete clause, USP is again in a position to develop drug information. The MGEC expressed an interest in being involved in strategic planning discussions with the USP Board of Trustees (BoT) Drug Information (DI) Task Force. The DI Task Force has engaged to some extent in USP's Drug Information Consultations I and II held on July 27, 2005 and August 22, 2006, respectively, and is considering the various options that were presented. The DI Task Force will provide oversight and input into staff activities as they work with USP's volunteer groups—Council of Experts (especially the MGEC and Information Expert Committees) and the Council of the Convention and others to develop general ideas for further consideration.

**Discussion:**

- There was concern about the perception of diminishing value of the Model Guidelines (MGs) and Formulary Key Drug Types (FKDTs), therefore, the MGEC wanted to understand the DI Task Force's stance on USP's continued involvement in the area of drug information. The DI Task Force recognizes the wealth of drug information expertise and welcomes input from the Information Expert Committees.
- The Information Expert Committee members have the expertise, willingness, and desire to be active participants in discussions with the BoT and DI Task Force and to contribute to full discourse and decision-making on this issue.
- Potential drug information activities and recommendations for proceeding were discussed.
- The MGEC questioned whether or not USP realistically plans to continue providing drug information. The BoT has a strong interest in continuing these efforts and staff has been charged with the responsibility of developing tactical opportunities for the BoT to consider.
- **USP DI:**
  - *USP DI* was a sound idea but perhaps did not get the resources or growth opportunities that it needed; it may have been too comprehensive for general use.
  - *USP DI* also was viewed as ponderous, difficult to use, not effectively marketed, and unknown in practitioner circles.
  - *USP DI* was sold to Thomson Micromedex to avoid a major financial loss to USP. At one time, up to fifty USP staff supported the effort.
  - *USP DI* was a "start-up" idea that wasn't freed from compendial constraints and thus drained resources from USP's core business.

**Feedback/Discussion of Model Guidelines Version 3.0**

- The MG V3.0 drug list table is posted on the USP website at <http://www.usp.org/hqi/mmg/revisions.html>.

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- Comments received from the Centers for Medicare and Medicaid Services (CMS) were discussed.
- Some expressed concern that USP's role in creating the MGs has been less independent than perhaps imagined by Congress because of the contractual relationship with CMS.
- It must be determined whether the MGs are meant to serve as a formulary or as an independent, objective list of categories and classes.
- The goal of the MGEC is to follow the intent of the law by developing a classification system that is scientifically pure and sound. The best interests of the beneficiaries have been kept at the forefront during deliberations.
- Practicality and financial concerns also have been considered; the MGEC strives for objectivity while maintaining awareness of the impact of their decisions.
- It is important that USP maintains the level of unbiased excellence that the public expects.
- The increase in the number of FKDTs in V3.0 was due primarily to the inclusion of new FDA-approved drugs and oncology drugs that were not included in the previous version, and the separation of enzyme replacements by their indications.
- FKDTs continue to be an issue:
  - According to a recent CMS guidance, analysis of FKDTs during the formulary review process will be handled differently. Instead of requiring one drug from each FKDT on drug plan formularies, FKDTs will be used as an "outlier test," a term that is not fully defined. It could mean that the FKDTs are used to determine if there are any glaring holes in the formularies.
  - FKDTs were developed as a compromise to maintain a balance between assuring beneficiary access to the drugs they need and controlling cost through competitive bidding.
  - FKDTs also have a "logical imperative" that at times leads to only one drug in the FKDT grouping. For example, as new molecular entities (drugs or biologics) are developed that achieve efficacy through a new pharmacological mechanism of action, the likelihood is that initially there will be only one member in the group; however, as time goes on, other therapeutic alternatives that fit into the same grouping will emerge.
- Possible solutions to the change in FKDT status include:
  - Incorporating the FKDTs into the categories and classes, which was a consideration during development of the prior versions of the MGs; however, this solution may result in decreased utilization of the MGs by drug plans. Because the MGs are a voluntary standard, plans have the choice of using it or the American Hospital Formulary Service (AHFS) or other classification system. However, this solution would ensure the MGs maintain the value of assuring beneficiary access. It also has a logical scientific basis (e.g., placement of enzyme inhibitors or vaccines into one pharmacological class to achieve competitive bidding is illogical because that is not how they are used or purchased).
  - Other solutions may emerge and be considered by the MGEC. For example, the groupings could be adjusted yearly to promote competitive bidding where cost is a major consideration after safety and efficacy issues are taken into account.
  - The larger issue for the MGEC is one of access. Is competitive bidding considered important for beneficiary access? It probably is not the case in the US given the way money is allocated, but it is certainly true for less affluent countries.
  - Obtaining feedback from CMS regarding the reasons that plans are decreasingly using the MGs. Are plans displeased with the increasing number of FKDTs? What drugs lead to the most frequent requests for deviations or use of clinical justifications?
  - Asking the BoT and Congress to be released from this activity or do it *pro bono*.
    - This suggestion was not supported. It is believed that the MGs provide value and are a medium to create balance.
    - The interests of patients have been the major focus; however, ideals do not match reality.
    - Communication with CMS was recommended to determine which drugs the majority of plans are excluding and what aspects of the MGs and FKDTs are most problematic for CMS.
- It was suggested that the AHFS classification system be compared with the MGs. However, it was noted that a detailed analysis of this system, along with the Veterans Administration (VA) Codes and the Medicare Prescription Drug Card list, was part of the initial MGs development process.
- To begin work on MG V4.0, it was suggested that representatives from CMS and drug plans (or a pharmacy benefit manager [PBM]) be invited to talk to the MGEC, focusing on the challenges they face related to the MGs and FKDTs as they begin to plan for the next benefit year.
  - A Congressional representative could be invited to explain the intent of the law.
  - Consider reaching out to beneficiaries and providers, who are also stakeholders in the process.



- The current system puts providers, patients, and payers into conflict with each other.

#### **CMS Contract**

- The terms of the cooperative agreement between CMS and USP, which extends from March 1, 2007 to February 29, 2008, were discussed.

#### **Workplan to Create Model Guidelines Version 4.0**

- The timeline for V4.0 will be similar to the timeline for V3.0. The public comment period will extend from mid-October to mid-November 2007, with the final deliverable due in early February 2008.
- The MGEC will continue to meet quarterly. Planning will begin for a robust meeting with guests from CMS and drug plans in August 2007.
- MGEC members will work with their Expert Committees to determine placement of new Part D–eligible FDA approvals.

#### ***Annals of Internal Medicine***

- During the last cycle, the Information Expert Committees were given the opportunity to develop articles for publication in the *Annals of Internal Medicine* (AIM). The goal of this collaboration was to reinvigorate the drug topics section of *Annals*. *Annals* was supposed to have created a special drug information section that gave recognition to USP.
- USP worked with *Annals* editors and the Information Expert Committees to create a list of topics for the proposed articles.
- The general idea was to submit approximately four papers per year to *Annals* from the Information Expert Committees.
- Two articles have been published to date: the first was on the history of USP and the initial creation of the MGs, and the second was the first part of a three-part series on pharmacogenetics/pharmacogenomics (PG/PG). The second article originated from a PG/PG network with no attribution given to USP.
- The results of the collaboration with AIM have not met the intended goals for various reasons.
- USP staff will continue to work with the committees and the *Annals* editors to facilitate publication of the articles currently in the pipeline.
- There may be value in writing a follow-up article that discusses the impact of the MGs.
- USP staff will work with *Annals* editors to reinvigorate the list of topics, considering addition of patient safety as a topic.

#### **Challenges and Opportunities**

- USP is working with a consultant who is looking at opportunities for re-engagement in drug information.
- The BoT is most interested in projects targeted toward practitioners; however, submission of other ideas was encouraged.

#### **Adjournment**

The participants were thanked for a productive meeting, and the meeting was adjourned.

