



U.S. Pharmacopeia
The Standard of Quality™

2005-2010 Council of Experts
Model Guidelines Expert Committee (MGEC)
Meeting #7
Monday, August 21, 2006
North Bethesda Marriott Hotel and Conference Center

Public Record of Meeting

Goals and Anticipated Outcomes

1. To discuss the Work Plan of the MGEC
2. To determine next steps and action items

Opening and Procedural Matters

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

The minutes from the previous meeting held on March 28, 2006 were reviewed and approved.

The meeting agenda was reviewed and approved.

Work Plan

Deliverables for CMS

The details regarding the new one-year contract between USP and the Centers for Medicare and Medicaid Services (CMS) were discussed.

Discussion

- Three to four years from now, the continued use of an Excel spreadsheet to capture changes to the Model Guidelines (MGs) will be cumbersome. A database needs to be created to track changes to the MGs as well as all comments and MGEC decisions.
- Resources for such an endeavor were discussed.
- The MGEC is already being asked to reconstitute decisions that were made in the past. This can be accomplished through the use of previous drafts of the MGs.
- A record of the rationale for MGEC decisions is needed.
- The idea for such a database will be explored, and an estimated cost and source of funding determined.

Collaboration with Information Expert Committees

A new process will be used to facilitate communication between Information Expert Committees. Information Expert Committee Chairs should send communications for other Expert Committees to USP staff, who will relay the communication to the appropriate Expert Committee.

Discussion

- One-year of overlap of Expert Committee chairmanships would be helpful. In the first year of each new cycle the outgoing Chair could remain on the Committee to mentor the newly elected Chair.
- Rolling elections for all Expert Committees are being considered by USP leadership.

Timeline and Meetings for Version 3.0

- The next teleconference, which will focus on the framing of Version 3.0, will be held on October 23, 2006.
- The next face-to-face meeting is scheduled for January 8, 2007 at USP Headquarters.

Discussion

- Speakers who could be asked to present at the January 2007 meeting were discussed.
- The need to limit the number of speakers in order to accomplish the work at hand was discussed.

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- December 10, 2006 is the deadline for public comments.
 - Public comments could be discussed by the MGEC by teleconference.
 - The MGs have recently been implemented by healthcare plans. Few public comments have been received. When the next revision is posted for public comment, healthcare plans will have used the MGs for a period of time and could submit more comments.
 - Comments also may be received from Expert Committee Members.
- If major changes are made, healthcare plans may not choose to use the MGs for the next coverage year.
- Over past few months, CMS has asked healthcare plans to justify gaps in their formularies.
- Decision making will be intensified as a result of convening the Information Expert Committees.
- A face-to-face meeting may be needed this fall to make the intense decisions before January 8th. The January 8th meeting could be a teleconference.

Preparation for the Drug Information Consultation II

An overview of the speakers who were scheduled for the August 22, 2006 Drug Information Consultation II was presented.

- The Drug Consultation II is designed to give participants the opportunity to communicate their drug information needs to USP.
- The morning panelists will focus on the new world of drug information. The afternoon speakers will represent doctors, pharmacists, and nurses.
- USP is considering entering into a partnership with other organizations to produce drug information.
- This could be the start of a new drug information service collaboration.
- A Board of Trustees meeting will be held on August 22, 2006 immediately after the Drug Information Consultation II. Representatives of physician, nursing, pharmacist, and consumer groups will be present. A representative from the MGEC also will be in attendance.

Discussion

Information Expert Committee Members

- Passion and an urgency to provide valuable drug information were evident during the Information Expert Committee Orientation.
- The vision to expand USP drug information activities should be communicated to Information Expert Committee Members as soon as possible to motivate them.

Partnerships and Next Steps

- USP's vision for drug information activities needs to be clarified and a proposal created. The proposal may be shown to various organizations who might be interested in partnering with USP.
- Partnership opportunities also may be discussed with governing boards of other professional organizations.
- A marketing assessment to evaluate the impact of the activity should be conducted and used to develop a robust business plan.
- Planning could take six to eight months, with outcomes expected within three years.
- The initial step should entail collaborative planning with the potential partner organizations.
- Organizations active in the quality movement could be asked to support the endeavor.

Drug Information Needs

- Drug information is multidisciplinary – there is no product or service currently available that meets everyone's needs.
- As managed care plans get more sophisticated, consumers need other sources of information to balance the marketing materials they are being exposed to.
- There is a lack of standardization in the presentation of drug information.
- Forming partnerships to duplicate drug information that is already available in the marketplace would not be valuable.
- A USP product could be the successor to ePocrates, the source of drug information most commonly used for active prescribing. People should rely on the best source of information.
- A credible and consistent source of information is needed for training programs.

Next Steps and Action Items

- For record keeping purposes, the orientation session will become the first meeting of each Information Expert Committee.

- The first order of business for the second meeting of each Information Expert Committee should be the election of a Vice-Chair.

Adjournment

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