June 7, 2007

Council delegates present:

Deborah Nadzam, Chair
Carla McSpadden (ASCP), Vice Chair
Diane Cousins (USP), Secretary
Lee Rucker (AARP)
Joe Cranston (AMA)
Rita Munley Gallagher (ANA)
James Owen (APhA)
Bona Benjamin (ASHP)
Ellen Quinn (ASHRM)
Carol Holquist (FDA)
Sal Peritore (GPhA)
Frank Federico (IHI)
Matt Grissinger (ISMP)
Linda Hanold (The Joint Commission)
Eleni Anagnostiadis (NABP)
Ray Bullman (NCPIE)
Rosemary Cook (PhRMA)
Jeff Ramirez (VA)
Elizabeth Miller (Liaison to USP's SMU EC)

Alternates attending with their delegates:

Kasey Thompson (ASHP)
Mary Gross (FDA)

Organizations/Members not represented:

AHA
DoD
NASPA
NCSBN
NPSF

Observers

Lindsey Davidson (ASCP student)
Karyn Downie (AAHSA)

The Vice Chair welcomed Council members, alternates, and guests and called the meeting to order at 1:50 p.m.

- It was moved, seconded, and unanimously passed to accept the summary of the February 2007 meeting.
- Due to the hardship incurred by some delegates of taking two days from their schedules to attend meetings, it was decided to test the feasibility of concluding all Council business during a one-day meeting. Therefore, the next Council meeting will be on Thursday, October 11, 8 a.m.-3 p.m. Reactions to that meeting schedule will determine whether Council meetings remain with the one-day format or return to two days.

Action Item: USP's VOA department will make arrangements to change the October meeting from a two-day to a one-day meeting.

The Chair congratulated the Council on winning the APhA Foundation's Pinnacle Award and thanked Rita Munley Gallagher for her efforts in compiling the paperwork necessary for the nomination and application. Kudos were also given to Dr. Gallagher for recognition of her exceptional service by the Association of State and Territorial Directors of Nursing (ASTDN).

Secretary's Report

- Ms. Diane Cousins announced that the proposal to lengthen the tern of service of the Chair and Vice Chair from one year to two years was approved.
- Dr. Gallagher explained the rationale for standardizing the format of Council recommendations and statements. The templates were discussed, with the sections Background, Definitions, and References to be included as appropriate. Council "Statements" are to be considered position statements, rather than policy statements. It was moved, seconded, and unanimously approved to accept the new templates for Council recommendations and statements.

Membership

Karyn Downie presented on behalf of the American Association of Homes and Services for the Aging in its petition for Council membership. It was moved, seconded, and unanimously passed to accept the AAHSA as a member in the Health Systems Organization category for a two-year term.

Action Item: The Secretary will send a letter to AAHSA welcoming it as a new member of the Council.

Subcommittee Reports:

- Taxonomy –*Rita Munley Gallagher and Ellen Quinn, Co-chairs*

No report.

- Technology – *Matthew Grissinger, Chair*

Mr. Grissinger reviewed the latest draft of the At-Risk Behaviors paper with the Council. Table 1 will be relabeled to reflect that it characterizes behaviors that were reviewed for this paper and the list of behaviors was created specifically for this endeavor. The Council will review the editorial changes on Day 2.

Action Item: Mr. Grissinger will make the suggested editorial changes for Council review on Day 2.

- Practice Related Issues – *Carla Saxton-McSpadden, Chair*

No report.

- Promoting, Monitoring & Evaluating — *Deborah Nadzam, Chair*

No report.

Update of Council Recommendations

- Bar Coding

Discussion on updating these recommendations and including expiration date and lot number revealed members' diverse attitudes toward changing any part of the recommendations. Ms. Benjamin maintained that the lot number should continue to be included as it is a very important patient safety element that becomes significant during drug recalls. Ms. Cook stated that PhRMA did not approve any changes in the recommendations and she would have to vet any suggested changes with PhRMA's membership. The Council questioned why it should be recommending

more specific labeling when it has yet to address the lack of utilization and implementation of bar coding technology. In general, the Council felt that it was establishing ideals of bar coding, not regulations. Options available to the Council included (1) table and bring up at next meeting, when a member of PhRMA is available to discuss, (2) proceed with the vote, and (3) leave recommendations as they are. It was moved, seconded, and approved to table discussion of the bar coding recommendations until the October 11 meeting.

Action Item: The Secretary will invite Alan Goldhammer to attend the October meeting to discuss PhRMA's objections to the revisions to the bar coding recommendations.

- Health Care Organizations

The portion of the original recommendation referring to pharmaceutical storage systems was deleted and a sentence was added to ensure that machine readability validity must meet industry quality standards. It was moved, seconded, and unanimously approved to accept the recommendations as amended.

- Manufacturers

Minor editorial changes were made to the recommendations. It was moved, seconded, and unanimously approved to accept the recommendations as amended.

- Culture

Dr. Nadzam will prepare draft recommendations regarding culture for Council review and discussion at the October meeting.

- Storage

Ms. McSpadden will prepare draft recommendations regarding storage of pharmaceuticals for Council review and discussion at the October meeting

Action Item: Deborah Nadzam will draft recommendations related to culture for Council review and discussion at the October meeting.

Action Item: Carla Saxton-McSpadden will draft recommendations for storage of pharmaceuticals for Council review and discussion at the October meeting.

Drug Samples

The majority of members decided that enough data exists for the Council to go forward with recommendations concerning drug samples. Ms. Cousins presented the latest version of the recommendations, having incorporated comments received from members. It was suggested that the recommendations be grouped according to topic (manufacturer, labeling, patients, etc.). None of the proposed recommendations addresses issues involved with appropriate storage in physicians' offices and Ms. Cook stated that more research is needed to maintain the Council's credibility. Ms. Hanold expressed the view of the Council in stating that the use of drug samples should parallel the best practices of handling prescription medications. It was suggested that the Council take a proactive approach to avoid errors by developing recommendations for preventing medication errors. No vote was taken but members were asked to review the proposed recommendations and forward any specific comments to Ms. Cousins for Draft 3 within the next two weeks.

Ms. McSpadden reported on the possible creation by the National Council for Prescription Drug Programs (NCPDP) of an electronic standard for the handling and/or dispensing of medication sampling activities. The standard would support the electronic data flow and facilitate how samples are managed, tracked, etc. Patient safety would be enhanced because the electronic history would include a patient medical history that would include any samples dispensed and could be transferred at any time to the point of care.

The meeting was adjourned at 5:00 p.m.

June 8, 2007

Council Delegates Present:

Deborah Nadzam, Chair	Carol Holquist (FDA)
Carla McSpadden (ASCP), Vice Chair	Sal Peritore (GPhA)
Diane Cousins (USP), Secretary	Frank Federico (IHI)
Lee Rucker (AARP)	Matt Grissinger (ISMP)
Karyn Downie (AAHSA)	Linda Hanold (Joint Commission)
Joe Cranston (AMA)	Eleni Anagnostiadis (NABP)
Rita Munley Gallagher (ANA)	Ray Bullman (NCPIE)
Bona Benjamin (ASHP)	Jeff Ramirez (VA)
Ellen Quinn (ASHRM)	Elizabeth Miller (Liaison to USP's SMU EC)

Alternates attending as representatives of their organizations:
Rosemary Cook (PhRMA)

Alternates attending with their delegates:
Mary Gross (FDA)
Shawn Becker (USP)

Organizations/Members not represented:

AHA	NASPA
APhA	NCSBN
DoD	NPSF

Observers:
Denise Toyer (FDA)
Lindsey Davidson (ASCP Student)

Action Item: Laura Provan, USP Director of Corporate Communications, will develop a press release about the Council's receipt of APhA's Pinnacle Award.

At-Risk Behaviors (Continued)

Mr. Grissinger presented a review of changes to the position paper. It was moved, seconded, and approved to accept the paper as amended.

Drug Suffix Conference Summary

Ms. Hanold and her workgroup were not fully comfortable with the way the "Factors Potentially Contributing to the Problem" and "Suggested Strategies/Interventions to Address Current Concerns for Consideration" discussion points were presented in the draft summary and requested the Council's guidance on how to improve the presentation of these sections. Options included labeling the bullet points as brainstorming ideas, condensing some bullets into table format, and

writing some bullets as paragraphs. It was recommended that the summary should indicate that the speakers were notified and asked to verify the accuracy of their presentations.

Action Item: Ms. Hanold will reword the Factors and Strategies sections of the summary with the assistance of Ms. Gross, Mr. Grissinger, & Ms. Cook. It will be sent out to the Council by July 16 for review and ballot.

Drug Suffix Conference Recommendations

There was a question as to whether over-the-counter (OTC) drugs should be included in the recommendations derived from this conference. Ms. Cook stated that the organization representing the OTC drug industry is not represented on the Council and the issue was not a major topic of the conference. From its inception, the Council has focused on prescription medication, rather than OTC drugs. The Council determined to word the recommendations more strongly (i.e., "should collaborate" rather than "should consider") and to separate the recommendations into two sections – one for immediate actions related to front line practitioners and the other for long term, call to action items for appropriate stakeholders.

Action Item: Ms. Hanold will rework the recommendations and forward them for Council review by mid-July.

Drug Suffix Conference Survey

Several changes were suggested for the survey, which will be made before the survey is sent out to the Council for review. Mr. Grissinger asked for feedback by July 1. He will then be in contact with USP staff for review and finalization. A test version will be sent to members before being posted on Survey Monkey.

Action Item: After receiving feedback from members by July 1, Mr. Grissinger will confer with a USP survey specialist to finalize the survey and then forward to Ms. Hanold for posting.

Action Item: Ms. Hanold will post the test version of the survey for member review and then post on Survey Monkey after July 15.

A draft press release will be issued for Council review when the summary is completed.

Strategic Planning

The floor was opened to ideas and suggestions for future Council projects. Included on the list were:

- Medication reconciliation
- In-house reporting systems
- Curriculum training regarding medication errors to include the following components:
    1. human factors
    2. at-risk behaviors
    3. in-house reporting could include the ISMP self assessment and MEDMARX®
- Developing recommendations to implement technology related to the prevention of medication errors

- Human factors
- A follow-up conference on bar coding
- Strategies to reduce errors using the Wikipedia format

Mr. Federico stated that two levels of technology recommendations are needed – one for senior leadership and one for front-line practitioners. Too often there is only partial implementation of recommendations because of a lack of senior leadership support. Council members were asked to identify the issues they considered most relevant. The top issues were (1) medication reconciliation, (2) in-house reporting systems, and (3) a tie for core curriculum training and technology recommendations.

Roundtable Updates: The following member organizations submitted written reports for inclusion in the meeting summary:

ASHRM (Ellen Quinn) – ASHRM has unveiled its new logo, emphasizing healthcare risk management. The annual conference is scheduled for October 10-13 in Chicago. As a pre-conference attraction, on October 9 USP and ISMP will be conducting a combined workshop on using data effectively to manage medication safety risks. June 18-22 is Healthcare Risk Management Week during which all healthcare risk managers are encouraged to develop and present programs relating to patient safety.

USP (Diane Cousins) – More than 500 comments have been received at USP regarding the proposed revisions of General Chapter <797>. USP will be conducting widespread outreach to explain the final revisions. For the first time, USP's Annual Scientific Meeting will include a Quality of Care track. Ms. Hanold will be presenting on the drug suffixes conference and USP will conduct a session on the salt nomenclature policy. Two RFAs have been issued related to the Patient Safety Quality Improvement Act: one establishing a privacy and confidentiality center to scrub data and the other to establish a network of patient safety databases that would analyze and disseminate data, update a national taxonomy, and set standards.

USP's Safe Medication Use Expert Committee (Elizabeth Miller for Mick Murray) – The Safe Medication Use Expert Committee has received more than 1800 hits to its online survey to gauge awareness, perception, and effectiveness of the use of tall man lettering by manufacturers and vendors. Member organizations were asked to disseminate the survey to their individual members via e-mail or their electronic newsletters and on their websites.

The meeting was adjourned at 1:12 p.m.