February 25, 2005

Council delegates present:

Linda Hanold (JCAHO), Chair
Diane Cousins (USP), Secretary
Lee Rucker (AARP)
Rita Munley Gallagher (ANA)
Ellen Quinn (ASHRM)
Carla Saxton (ASCP)
Ron Nosek (DoD)
Carol Holquist (FDA)
Eleni Anagnostiadis (NABP)
Ray Bullman (NCPIE)
William Kelly (ex officio)

Council delegate participating by phone:

Deborah Nadzam

Alternates attending as representatives of their organizations:

Teresa Rubio (ASHP)
Stefan Merlo (NACDS)
Rosemary Cook (PhRMA)

Alternates attending with their delegates:

Mary Gross (FDA)
Shawn Becker (USP)

Organizations/Members Not Represented:

AHA	David Kotzin
AHCA	GPhA
AMA	HDMA
AONE	ISMP
APhA	NCSBN

Others attending representing their organization:

Lynn Sanders (VA)

Observers:

Anna Zhao-Wong, MD, PhD (FDA)
Susan Camp (USP)
Rick Schnatz (USP)
Sue Zmuda (USP)

Linda Hanold (JCAHO), Chair, welcomed Council members and guests, and called the meeting to order. Ms. Hanold announced that the current roster of delegates and alternates would be forwarded by e-mail for any necessary corrections. She also suggested that each organization identify a primary and alternate delegate before the next meeting if they have not done so already. Ballots for the meeting summary of the September 2004 meeting are required, so Ms. Hanold reminded delegates to submit their ballots immediately if they have not already done so. Mary Gross (FDA) made an announcement regarding an upcoming FDA advisory meeting being held on March 7th to address the issue of color on pharmaceutical products. Several delegates indicated planned participation.

Secretary's Report: *Diane Cousins (USP)*
Diane Cousins reported that questions were raised concerning UHC's use of the Taxonomy and the fact that the classification is being used without attribution because UHC believes it is no longer a derivative product of the Council's work. It was suggested that a face to face dialog may be beneficial in resolving questions of use. ASHP and several members offered to contact UHC on behalf of the Council. There was also discussion on the legality of pursuing UHC on the copyright issue.

ACTION ITEM: Diane Cousins will send a letter to UHC under the Chair's signature regarding its continued use of the Taxonomy and the Council's expectation of attribution as a derivative work.

Ms. Cousins reported that there has been no communication with SEFH, despite numerous attempts on the part of the Council. Therefore, SEFH was notified in December 2004 that its membership on the Council had been revoked. She also reported that The National Patient Safety Foundation (NPSF) made contact and explained that it had completed an extensive internal reorganization and as a result has requested to rejoin the Council. It was moved and carried to reinstate NPSF as a Consumer Organization in the At Large Membership category for a 2-year term. Diane Pinakiewicz, President of NPSF, will serve as Delegate to the Council.
Ms. Cousins also reported on the Canadian Medication Incident Reporting and Prevention System, which she explained as a collaborative initiative between CIHI, ISMP Canada, and Health Canada. An initial draft of information requirements and descriptors for medication incident reporting and prevention was identified and presented to the Council. Their next steps will include developing a minimum data standard for use by hospitals to report medication incidents and to identify and document business, technical, and functional requirements necessary to direct this effort. CIHI has requested to use the NCC MERP definition of medication error and Category Index in this reporting system. They propose replacing error with incident. Categories A and D included minor changes. They also proposed three changes to the medication error definition: (1) replacing "error" with "incident", (2) replacing "such events" with "medication incidents", and (3) replacing "healthcare" with "drug".

ACTION ITEM: The Council approved the use of the definition of medication error with changes and the Category Index was approved with changes. CIHI was requested to provide the Council feedback in 6-12 months.

Subcommittee Reports:

- **Taxonomy**—— *Ellen Quinn (ASHRM) and Rita Munley Gallagher (ANA), Co-chairs.*

The Subcommittee presented the Council with an evaluation of the possibility of dividing Category B errors into subcategories B-1 (chance) and B-2 (action). For the period January 1, 1999-September 30, 2004, there were 149 randomly selected Category B errors from the Medication Errors Reporting (MER) Program and 374 randomly selected Category B errors from the MEDMARX® program for the period March 18, 2000-March 17,

2004. Initial review indicated that of the records chosen, 36 were actually Category C errors. Based on review, Category B will not be changed.

The Taxonomy Subcommittee was also asked to draft principles for the partial use of the Taxonomy. It started from the premise that the Council copyrighted the Taxonomy in 1998 and, therefore, holds all rights reserved. The Council's intent is that the Taxonomy be widely accessible and included in organizational policies and procedures that improve patient safety. Ideally, the Taxonomy should be reproduced in its entirety and without alteration. This is currently allowable without special permission from the Council when used by individual health care facilities for internal non-commercial use. In some instances, however, an entity may have valid reasons for wanting to utilize selected elements of the Taxonomy or to adapt portions for a specific purpose. The Council evaluates these requests on an individual basis and either recommends or denies partial use of the Taxonomy. Use of the Taxonomy requires Council attribution and requests statistical and anecdotal feedback regarding any development of patient safety strategies.
It was suggested that there be three versions of the Taxonomy to cover all possible situations. This will be included in the draft principles.
The World Health Organization (WHO) is developing its own taxonomy and has received several taxonomies from around the world. After discussion, the Council moved and approved taking a proactive approach and submitting the NCC MERP Taxonomy to WHO for consideration.

ACTION ITEMS:
Rita Munley Gallagher and Ellen Quinn will draft a narrative document that describes principles to guide partial use of the Taxonomy for review and approval at the June meeting.

Ellen Quinn will follow up on the use of the Taxonomy with Stars and RiskMaster and provide the Council with corporate contact names and web links at the June meeting.

The PME Subcommittee will perform a search of Taxonomy users and develop a database that will allow Council communication with users.

NCSBN will obtain feedback on its use of the Taxonomy and report at the June meeting.

Linda Hanold will provide standards-setting verbiage for the principles that will guide use of the Taxonomy.

Taxonomy subcommittee will review the results of the Ohio State University validity study of the interpretation of the Category Index as used in the USP MEDMARX Program for its potential application or revisions to the current NCC MERP Categorization Index.

The Secretary will draft a letter to WHO that provides background about the Council and provides a copy of its current taxonomy for medication errors as a proactive effort for WHO's consideration in developing their taxonomy.

- **Practice Related Issues** - *Carla Saxton (ASCP), Chair*

Ms. Saxton introduced the revised recommendations on the writing, dispensing, and administration of medicines to the Council. Several final suggestions were made for inclusion. Ms. Saxton will finalize the recommendations and send out via e-mail to the delegates for balloting.

ACTION ITEM: Carla Saxton will finalize the recommendations and distribute via e-mail to all delegates for a vote.

- **Promoting, Monitoring, and Evaluating -** *Deborah Nadzam, Chair*

Dr. Nadzam presented the Council with a proposed outline for the 10-Year Anniversary Report and a draft for a Dear Editor letter to elicit publication. The purpose of the report is to summarize the history of the Council, its work to date, and the impact this work has had in the area of medication error reporting and prevention. Several sections (history, taxonomy, recommendations, and the bar coding conference) have already been submitted to the subcommittee. Some members have also submitted statements describing the impact Council activities have had on their organizations. When all materials have been compiled, they will be forwarded to the entire Council for comment and approval. Shawn Becker was asked to e-mail the documents to all members.
Dr. Nadzam received a request to provide a statement on the NCC MERP, with a link to web site, from the Pharmacy Purchasing & Products Magazine. Considerable discussion ensued because many Council members were not familiar with the requesting organization. The organizations web site was reviewed by the membership and it was agreed that a statement and link would be provided.

ACTION ITEMS:
Shawn Becker will forward the Dear Editor letter and the 10-year report document to the Council for comment. Members will provide comments by return e-mail.

Secretary will review and revise the statement for PPPMAG web site and forward statement and link via e-mail.

Linda Hanold introduced several items for discussion:

Use of Sample Medications
Linda Hanold (JCAHO) has been in communication with Julia Rhodes of Rx Consultant regarding the use of drug product samples and informed her that the Council does not endorse specific products. As there is currently no record-keeping of product samples, it is difficult to determine the extent of medication errors associated with their use. Considering the number of sample medications given out daily and the possibility of errors resulting from indiscriminate distribution, Ms. Hanold inquired whether or not this was a topic that should be taken up as a Council issue with resultant Council recommendations. PhRMA indicated that there may be anti-trust issues involved.

ACTION ITEM: USP CAPS will obtain data from the MEDMARX and MER databases on errors resulting from the use of sample medications to present at the June meeting. ISMP will review their Safety Alerts for information on sample medication problems also.

Vendors Presentations to Council
Vendors requesting to present before the Council should provide sufficient information for their requests to be evaluated. Currently, such requests are forwarded to the appropriate subcommittee for assessment and then the subcommittee's recommendations are brought before the Council for discussion and approval.

Use of Suffixes in Drug Names
Using a suffix to designate a modified dosage formulation is a common occurrence but there are no uniform standards or consistent definitions concerning what these suffixes mean or how they are used. The Council has determined that this issue of non-standardized use of drug suffixes has such ramifications for patient safety that it elected to convene a roundtable meeting with invited stakeholders to be held in October, 2005. The Council membership agreed that a statement of the issues should be released prior to the October meeting. Linda Hanold has been in contact with Ms. Gibson from the Robert Wood Johnson Foundation regarding support for the conference. Additional funding sources will be investigated by Council members. The model for this conference will be similar to the one used for the bar coding conference in 2000. A literature search should be conducted to assess what has been addressed regarding this topic prior to the next scheduled Ad hoc conference call. During that call speakers will be identified and arrangements and logistics completed.

ACTION ITEMS:
Linda Hanold will perform a literature search pertaining to drug suffixes.

Carol Holquist and Mary Gross will modify the drug suffixes issue statement for comment by the Council prior to the June meeting.

Linda Hanold will develop a budget for the drug suffixes conference.

The Secretary will forward the slides that Scott Dallas' presented on the Medication Errors Involving Drug Suffixes at the September 2004 meeting to Lee Rucker.

FDA Request for Definitions for MEDRA Users – *Carol Holquist, FDA*
The FDA has requested that the Council provide definitions for MedDRA terms that are used by the pharmaceutical industry. These terms included overdose vs. underdose, stages of medication errors, dosage form, drug formation, dose omission vs. underdose vs. inappropriate schedule, dose vs. dosage, drug, rate vs. duration vs. schedule, and technique vs. preparation. Currently, the Council has no written definitions for these terms. All Council members were asked to forward any definitions they deem appropriate to Carol Holquist.

ACTION ITEM: Individual organization will forward any definitions they are currently using to Carol Holquist, who will develop formal definitions per the Council's discussion.

Roundtable Summaries Provided in Writing by Delegates

AARP – Current activities surrounding prescription drugs focus on three areas: (1) educating older adults and caregivers about the new Medicare drug benefit and helping

them to make informed choices during the upcoming enrollment period; (2) making evidence-based research on pharmaceuticals (conducted by the Evidence-based Practice Center at the Oregon Health & Science University) accessible to consumers through http://www.aarp.org; and (3) preparing for a re-launch of AARP's "Wise Use" campaign to promote wise purchasing and safe appropriate use of medicines.

AONE – No activities to report.

ASCP – Since the last meeting, ASCP presented an educational program on medication errors at its Annual Meeting in November. ASCP has continued its leadership task force on patient safety and quality assurance. This is the second year for this task force and the focus of this group is predominately internal pharmacy error occurring in long-term care pharmacies. The work of this group is just getting started and progress reports will be shared with the Council in the future. Carla Saxton has completed an article on drug suffixes based on the presentation at the previous Council meeting. This article will be published in an upcoming edition of the ASCP journal. ASCP is also working on the Medicare Part D benefit, attempting to educate and disseminate ever-changing information on this new benefit. ASCP held an audio conference (archived online), conducted Congressional visits and briefings for members, and a meeting for potential prescription drug plans (PDPs) on the impact of the benefit in long-term care settings.

ASHRM – In addition to the numerous programs, publications, and products currently offered by ASHRM, a number of specific initiatives will be developed in 2005 as part of the ASHRM strategic Plan. These initiatives are supported by the findings of 2004 Membership Survey and are consistent with the professional core contributions of its membership. These include (1) conducting unique professional development opportunities on Quality, Patient Safety, and Risk Financing topics; (2) emphasizing ASHRM as a "learning organization"; and (3) launching risk management interest networks. The survey also identified "hot" issues that ASHRM should pursue: collaboration with other organizations, development of web-based education, and engaging ASHRM chapter leaders and members in ASHRM activities.

NCSBN – In January, NCSBN began administering the NCLEX in Seoul, Hong Kong, and London. More than 1000 tests have been taken so far in these locations. All nurses must make application for licensure from a member board before being granted authorization to test. The Practical Nurses passing standard for passing the NCLEX examination was raised. NCSBN now has 119 states in the Nurse Licensure Compact. The TERCAP project, which analyzes nursing errors from a regulatory point of view, is on target for publication this fall. This project utilized some of the methodology from the NCC MERP Taxonomy.

USP – USP introduced its 5-year program cycle and renamed the Quinquennial Meeting as simply the USP "Convention". The Convention was held March 9-13, 2005, at the Grand Hyatt in Washington, D.C. A new Board of Trustees was elected; and 13 resolutions were passed, four of which are related to patient safety.

There being no new business, Ms. Hanold adjourned the meeting at 1:55 p.m.