February 23, 2006

Council delegates present: Linda Hanold (JCAHO), Chair Diane Cousins (USP), Secretary Lee Rucker (AARP) Lyn Bentley (AHCA) Rita Munley Gallagher (ANA) Anne Burns (APhA) Carla Saxton (ASCP) Ellen Quinn (ASHRM)

Kasey Thompson (ASHP) Mike Datena (DoD) Carol Holquist (FDA) Sal Peritore (GPhA) Matt Grissinger (ISMP) Eleni Anagnostiadis (NABP) Ray Bullman (NCPIE) Deborah Nadzam

Alternates attending as representatives of their organizations: Kristin Hellquist (NCSBN) Lou Cobuzzi (VA)

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

Organizations/Members not represented:

AHA NPSF
AMA PhRMA
HDMA David Kotzin
Michael Murray (Chair, USP Safe Medication Use Expert Committee)

Observers:

Tara Modisett (NASPA/NASPAE) Nicole Mollenkopf (ISMP Guest) Rachel Riley (APhA Resident) Rebecca Snead (NASPA/NASPAE)

The Chair, Linda Hanold, welcomed Council members, alternates, and guests and called the meeting to order at 1:48 p.m. Introductions were made for all observers. Ms. Hanold announced that Roundtable reports must be submitted in writing to be included in future meeting summaries. She also announced that Joe Cranston and his voice of reason were sorely missed at the meeting. It was moved and seconded to accept the summary from the October meeting. With the change of Rich Del Pan as the FDA Director of Drug Safety instead of Steve Galson, the summary was approved.

Chair's Report

1. Ms. Hanold reported that the 10-Year Anniversary Report is officially on the NCC MERP website and that there have been 205 hits on the site since December. Several member organizations disclosed plans to use all or parts of the report in their newsletters or e-news.

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2. The meeting cancellation and notification policy was reviewed and the following decisions we made:

- A backup message would be placed on Diane Cousins' office voice mail.
- A call-in number for USP will be added to the calling tree.
- Members would be e-mailed if a decision to cancel was made before the close of business. Members were asked to indicate a preferred phone number for initial contact. It was suggested that the calling tree be laminated before being sent to Members.

Action Item: The Secretary will finalize the calling tree and have it laminated and sent to Council members.

- 3. Subcommittee assignments were deferred to Day 2.
- 4. Ms. Hanold debriefed the Council about the NCC MERP booth at the ASHP Mid-Year Meeting.
 - There were many interested visitors to the booth and kudos for the Council's work.
 - Several foreign visitors were interested in Council franchises and collaborating with the Council on implementing medication error reporting programs. This may be a future Council activity.
 - Copies of the 10-Year Anniversary Report were available for display and the Executive Summary was available for dissemination.

Ms. Hanold thanked ASHP for providing the booth for the Council and especially one with such a good location. In response to a question as to whether or not the booth was worthwhile, Ms. Hanold responded that it was definitely something that the Council could do at annual meetings and could even include sessions on medication safety but would need sponsoring from organizations.

Vice Chair's Report - Medicate Part D

Carla Saxton, Vice Chair, updated the Council on matters related to Medicare Part D. Formulary switching can be confusing even though dosing may be equivalent. Drugs on formularies may change and automatic substitutions may not have the same dosing regimens. It is premature to change the Council's taxonomy to include all generic substitutions because within the next few months new issues may arise. One role for the Council may be to have the taxonomy incorporated into the Quality Indicators. Formulary substitution issues are larger than just Medicare Part D; but for the present, the Council will focus on Medicare Part D with the possibility of sending a letter to CMS. There is a need to gather information that could lead to a set of formulary rules and recommendations in conjunction with CMS.

Action Item: The Practice Related Issues Subcommittee will gather information on the issue of formulary substitutions and report to the Council at the June meeting.

Secretary's Report

- 1. The American Hospital Association (AHA) was a founding member of the Council but has had no involvement in Council activities since John Combes retired as Delegate. AHA would like to remain a member and should have a Delegate named by March.
- 2. The Federation of State Medical Boards (FSMB) was invited to join the Council but, to date, there has not been a decision.
- 3. The Department of Defense requested and was granted permission to incorporate the Index for Categorizing Medication Errors and the Algorithm into its quarterly and annual reports. The National Board of State Medical Examiners requested and was granted permission for partial

Meeting Summary – Draft

use of the taxonomy categories and subcategories for a national survey on medication errors made by physicians.

- 4. It was approved unanimously to renew the membership of the American Society for HealthCare Risk Management, the Department of Defense, and the Department of Veterans Affairs for 2-year terms.
- 5. The National Alliance of State Pharmacy Associations (NASPA) applied for membership on the Council. Rebecca Snead, Executive Vice President and CEO gave a short presentation about NASPA, emphasizing its role in providing quality assurance services and educational programs to pharmacists and pharmacies throughout the United States. The Council felt that it did not have sufficient information about the organization and voted to table the membership decision until the June meeting at which time NASPA would give a 15-minute presentation.

Action Item: The Secretary will follow up with NASPA regarding its request for Council membership and request a formal presentation at the June meeting.

The Council determined that permanent criteria are needed for membership on the Council. Required standardized information might include the mission, purpose, and objectives of an organization, with the Council verifying its scope, reach, and membership. It was suggested that an addition to the Rules page of the website include a link to a membership application form. The Council will consider this before posting on the website.

In an effort to expand the demographic base of the Council from primarily pharmacists, the Secretary was requested to extend an invitation to the Institute for Healthcare Improvement to apply for membership.

Action Item: The Secretary will forward an invitation to apply for Council membership to the Institute for Healthcare Improvement.

Subcommittee Reports:

Taxonomy –*Rita Munley Gallagher and Ellen Quinn, Co-chairs* The Taxonomy Subcommittee was waiting to review a final version of the National Quality Forum taxonomy before making recommendations to the Council. Its report was deferred to the June meeting.

➤ Technology

Matt Grissinger reported that the at-risk behaviors draft is consistent with previous white paper formats and is ready for review by the Council. Discussion revealed that more background information is needed to raise awareness of the problem. Some healthcare institutions do not recognize short cuts or work-arounds as at-risk behaviors so the phrase needs to be more explicitly defined. Risk managers and healthcare professionals constitute the main audience but information should be expanded to educate organizational leadership. The purpose of the paper is to help establish organizational culture to minimize risky behaviors.

ANSI-AAMI's international meeting is scheduled for March in Paris. The best action for the Council at this time is to continue to wait and see what develops.

> Promoting, Monitoring & Evaluating — Deborah Nadzam, Chair

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Members were asked to review the Fact Sheet and the enhancements of existing objectives for discussion on Day 2.

The meeting was adjourned at 5 p.m.

February 24, 2006

Linda Hanold, Chair (JCAHO) Carla Saxton, Vice Chair (ASCP) Diane Cousins, Secretary (USP) Lee Rucker (AARP) Lyn Bentley (AHCA) Rita Munley Gallagher (ANA) Ellen Quinn (ASHRM) Kasey Thompson (ASHP)

Mike Datena (DoD) Carol Holquist (FDA) Sal Peritore (GPhA) Matt Grissinger (ISMP) Eleni Anagnostiadis (NABP) Ray Bullman (NCPIE) Deborah Nadzam

Alternates attending as representatives of their organizations: Marcie Bough (APhA) Mary Gross (FDA)

Kristin Hellquist (NCSBN) Rosemary Cook (PhRMA) Louis Cobuzzi (VA)

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

Organizations/Members not represented:

AHA	NPS F
AMA	David Kotzin
HDMA	Michael Murray (Chair, USP Safe Medication Use Expert Committee)

Observers:

Nicole Mollenkopf (ISMP Guest) Rachel Riley (APhA Resident) Kellie Taylor (ISMP Fellow) Elizabeth Cowley (USP) Rick Schnatz (USP)

Ms. Hanold reconvened the meeting at 8:45 a.m. Members were reminded to complete calendars for scheduling the October 2006 meeting.

Unfinished Business

1. With minor changes, the fact sheet was accepted as a final product. An electronic copy will be sent to Members to include in newsletters and on web sites.

Action Item: The Secretary will finalize the fact sheet and forward to Members.

2. A revised version of the calling tree, incorporating the changes from Day 1, was reviewed by the Council. With the addition of indicating a preferred phone number, the Council voted approval of the calling tree. Members were urged to forward pertinent information to the Secretary for inclusion in the calling tree.

- 3. Discussion regarding the meeting cancellation policy included having the e-mail subject line incorporate "Meeting Cancelled" to be sure that Members notice it and that an e-mail should be sent from the Secretary, in addition to using the calling tree. This e-mail will include a call-in number for those unable to travel but who may wish to participate by phone.
- 4. The following bullets were added to item 6 of the Recommendations to Reduce Medication Errors Associated with Verbal Orders and Prescriptions.
 - a. In order to avoid confusion with drug name modifiers, such as prefixes and suffixes, additional spelling-assistance methods should be used (i.e., S as in Sam, X as in x-ray).
 - b. Whenever possible, the receiver of the order should **write** down the complete order or enter it into a computer, then **read** it back, and receive confirmation from the individual who gave the order or test result.
- 5. Diane Cousins reported that the workgroup looking into drug samples reviewed background materials on existing requirements and/or laws and had its first conference call. Minimum and specific distribution requirements were explored. It was found that only JCAHO has any recommendations or requirements; and, therefore, those will be used as reference. Several problems were exposed: handling after leaving the manufacturer, samples being off the radar for pharmacists checking drug interactions, and doctors not tracking lot numbers in case of recalls. The appropriate use of drug samples is a topic the Council should consider pursing, as the Council is not opposed to the use of samples. Rather, it is concerned with the problems associated with storage and handling. When physicians dispense samples, they are taking the role of pharmacists and should be under the same restrictions as pharmacists. Any medication information or education that is given with a prescription should be included with samples. Ms. Cousins informed the Council that drug disposal is becoming a major environmental issue.

Action Item: The Drug Samples workgroup will draft a background statement and recommendations for Council review at the next meeting.

Drug Suffix Workshop

Linda Hanold provided an explanation of the budget and expenses for the Drug Suffixes Workshop. Several members reported rude and threatening behavior from some reporters. The press policy will be revisited to prevent this from happening in the future. A statement will be issued at the start of any future Council events indicating that the Secretary will coordinate all press activity and speak for the Council. Members are free to speak for their organizations but not for the Council.

Action Item: The transcript of the Workshop will be forwarded to Linda Hanold, Joe Cranston, Carla Saxton, Kasey Thompson, and Shawn Becker to aid them in drafting a summary of the meeting.

Drug Suffix Workshop Recommendations

Discussion of recommendations resulting from the Workshop initially questioned whether the Council was ready to draft recommendations without the meeting summary and whether there are any recommendations to be made. The Recommendations Subgroup felt that there were both short and long term valid recommendations and its draft recommendations contained the thought process it employed to reach its conclusions. It was suggested that the Council generate a list (glossary) of brand names plus suffixes and definitions of what the suffixes mean. The potential exists to conduct a pilot study of 2-letter suffixes if this is something that the Council wants to pursue.

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PhRMA is formulating a good naming initiative that may include suffixes. It is currently internal; but as it becomes more robust, it may expand to the FDA, among others. The main issue is not the use of suffixes but the inappropriate use of suffixes. The issue could be expanded to include all modifiers. It was suggested that the Council tap into consumer focus groups for their input on the issue of modifiers. Reports of errors involving suffixes should be catalogued so that manufacturers, standards setters, and FDA can understand the scope of the problem. Linda Hanold volunteered to post a survey to evaluate the extent of the suffixes issue on Survey Monkey for 30-40 days.

Action Item: The subgroup will comb the workshop transcript and interface with others, as necessary, to develop version 2 of the recommendations.

Action Item: Matt Grissinger (Chair) will contact Tim Lesar to work with a group composed of Linda Hanold, Carol Holquist, and Matt, to draft survey questions for Council review at the June meeting.

Action Item: Carla Saxton will review all recommendations to include suffixes.

<u>*Roundtable Updates:*</u> The following member organizations submitted written reports for inclusion in the meeting summary:

AARP (Lee Rucker) – AARP is committed to helping Medicare beneficiaries (and their caregivers) become aware of, and understand, the new Part D drug benefit. AARP just released a new tool that helps walk people through Medicare's (online) "Plan Finder." This is available on AARP's website at

http://assets.aarp.org/www.aarp.org /articles/health/Plan_Finder.pdf. Further, AARP continues developing materials to help people use medications safely. These are now more easily accessed online at http://www.aarp.org/health/usingmeds. Throughout 2006, some AARP state offices will be featuring these materials alongside their Medicare Part D outreach sessions. In addition, health care issues will likely take on a high profile for AARP with the February announcement that the AARP Board President-Elect is Jennie Chin Hansen of California, who began her career in community and public health nursing. Details are available at

http://aarp.org/about_aarp/aarp_leadership/photos_bios.

• AHCA (Lyn Bentley) – AHCA has been very involved in multiple aspects of Medicare Part D. In relation to drug safety/medication errors, one of its concerns about Part D relates to assuring the integrity and safety of pharmaceutical services, drug administration, and avoidance of unnecessary drugs. For example, nursing facility requirements of participation under Medicare/Medicaid require that residents be free of unnecessary drugs. One of the criteria for "unnecessary" is continuation of a drug in the presence of adverse consequences. If a resident is taking a drug on the formulary that is causing an adverse consequence, the facility would contact the physician, who would then change the order. If the newly ordered drug is not on the formulary and it is not immediately approved and available, the resident is placed at risk of consequences and the facility is at risk of being found out of compliance with requirements. AHCA has brought these concerns to the attention of CMS and is jointly working to reach an agreeable and appropriate resolution. New survey guidance in this area will likely emphasize the safety and accuracy of pharmaceutical services, residents' drug regimens, and facilities' responsibility to assure the safety and integrity of related systems.

- ASHRM (Ellen Quinn) ASHRM is very interested in the NQF taxonomy paper and how it should be engaged in educating its members about it. ASHRM is focusing its 2006 efforts on education in general. The following educational offerings are scheduled: Disaster Preparedness: lessons learned in 2005, February 28; Risk Financing Bootcamp, March 28-29; Barton Modules, April 24-28; OPHRM exam prep course, April 26-27; and PE Safety Curriculum, May 22-25.
- NCPIE (Ray Bullman) The National Council on Patient Information and Education (NCPIE) is finalizing a report with recommendations to stakeholder groups who can contribute to meeting quality improvement goals by the end of 2006 for written drug information (referred to as Consumer Medicine Information or CMI) provided with prescriptions filled at community pharmacies. The target for distribution of the report/recommendations is March 2006. NCPIE's Executive Director, Ray Bullman, will present a session entitled "Ensuring Safe and Appropriate Medicine Use A View from Along the Patient Pathway," on Tuesday, April 25, 2006, in Las Vegas at a hospital-based conference entitled," Redesigning and Improving Patient Education," sponsored by the World Research Group. For information about the meeting, visit http://www.worldrg.com/conferences.
- USP (Diane Cousins) Diane Cousins was appointed to the NQF Taxonomy Standards Maintenance Committee. The MEDMARX[®] Annual Report was released in January and concentrates on medication errors in radiological services and in ICUs. A major finding was that most errors occurred during hand-offs. The next Annual Report will focus on peri-operative areas and is planned for a late fall release.
- VA (Lou Cobuzzi) The VA is reengineering pharmacy software to develop state-of-the-art prescribing, processing, documenting with comprehensive safety, criteria-for-use, and search capability. It is also examining the development of a mobile dispensing capability, using the latest Sateliter Technology, for implementation during disasters. The VA is moving toward a true national drug formulary without local additions that would ensure nationwide access to all approved medications for its mobile patient population and continues review of the National Drug Database to identify and circumvent potential adverse drug events.

The following member organizations provided oral reports to the Council:

ANA	ISMP
APhA	JCAHO
ASCP	PhRMA
ASHP	NABP
DoD	NCSBN
FDA	Deborah Nadzam
GPhA	

Council Structure

 The Chair reminded Members that there are currently four Council subcommittees and one strategic planning subcommittee. She asked the Council to consider whether these subcommittees are focused on the right issues or whether they should be redirected. Discussion on the direction the Council should take for the future was deferred to the June meeting.

- 2. Deborah Nadzam presented the Promoting, Monitoring, Evaluating Subcommittee's draft for a new mission statement. There was much discussion and the Council approved the following statement: The mission of the NCC MERP is to maximize the safe use of medications amongst all stakeholders and to increase awareness of medication errors through open communication, promotion of medication error prevention strategies, and increased reporting.
- 3. The Council agreed to three broad objectives that combined what is currently on the website.

Action Item: The PME Subcommittee will finalize the objectives, incorporating the wording suggested at the meeting, and present a final draft for a vote at the June meeting.

The Chair announced that future meeting will conclude at 2:00 p.m.

The meeting was adjourned at 2:05 p.m.