June 20, 2006

Council delegates present:

Linda Hanold (JCAHO), Chair Ellen Quinn (ASHRM) Diane Cousins (USP), Secretary Sal Peritore (GPhA) Lyn Bentley (AHCA) Matt Grissinger (ISMP) Joe Cranston (AMA) Polly Johnson (NCSBN)

Carla Saxton (ASCP) Deborah Nadzam

Michael Murray (Chair, USP Safe Medication Use Expert Committee)

Alternates attending as representatives of their organizations:

Mary Gross (FDA) Jon May (NABP)

Deborah Davidson (NCPIE)

Virginia Torrise (VA)

Alternates attending with their delegates:

Kristin Hellquist (NCSBN) Shawn Becker (USP)

Organizations/Members not represented:

AARP DoD AHA **HDMA** ANA **NPSF** APhA PhRMA **ASHP** David Kotzin

Observers:

Richard Poirier (ASCP Legislative Intern)

Scott Dallas (FDA) Rod Hicks (USP)

The Vice Chair welcomed Council members, alternates, and guests and called the meeting to order at 1:50 p.m. Introductions were made for all observers. In the absence of a quorum the vote to accept the February meeting summary was postponed.

Secretary's Report

- 1. Diane Cousins announced the election of Deborah Nadzam as Chair of the Council and Carla Saxton as Vice Chair for the 2006-2007 cycle.
- 2. The AHA seat has been vacant since September 2004. Diane Cousins contacted Don Nielson, who will follow up and appoint a delegate by the October meeting.
- 3. There has been no response to the Council's invitation to apply for membership from the Institute for Healthcare Improvement (IHI). Ms. Cousins will follow up in mid-July.

Action Item: Ms. Diane Cousins will follow up with IHI in mid-July regarding applying for membership on the Council.

- 4. The National Alliance of State Pharmacy Associations (NASPA) was unable to attend the June meeting for its scheduled presentation due to a conflict; however, it will make the presentation at the October meeting. The merger of NASPA and NASPAE should eliminate any confusion Council members had regarding the parent organization.
- 5. The National Quality Forum Consensus Report on Standardizing a Patient Safety Taxonomy was circulated. The Report looked at the taxonomy at a very high level. Ms. Cousins reported that no real progress has been made by the Maintenance Committee.
- 6. The Patient Safety Quality Improvement Act cannot be implemented until patient safety organizations (PSOs) are established. AHRQ is behind schedule in setting up the criteria for PSO but is looking to having the process finalized by the fall. A network of patient safety databases may be delayed because of a lack of standardization.
- 7. Ms. Cousins reviewed recent requests for the Council's work products. She circulated the March 2006 newsletter from the Delaware State Board of Pharmacy, which featured the Council's Index for Categorizing Medication Errors on the front page.

The Chair asked that all members fill out calendars for the winter meeting as soon as possible. She also requested that members consider the role of the subcommittees and whether they were comfortable with how the subcommittees are designed and operated.

- Technology Most issues involving technology are already being discussed within the medical community. Possible issues for future Council endeavors include: looking into the safe use of technology, errors resulting from technology, and error detection mechanisms for near misses.
- Practice Related Issues It was proposed that the Council look beyond acute care settings
 into the areas of non-acute settings, nursing homes, etc. A suggestion to expand the
 Council's role in training in academia led to a discussion about whether this issue should be
 part of the PME subcommittee or if it was important enough to have a subcommittee of its
 own.
- O Promoting, Monitoring, Evaluating To date, this subcommittee has focused on what the Council has accomplished in the past 10 years. The evaluation component has not been exercised to a great extent but could be engaged if education was incorporated into the subcommittee's purview. It was proposed that the Council pursue international efforts to promote reporting and preventing medication errors.

Subcommittee Reports:

➤ Taxonomy —*Rita Munley Gallagher and Ellen Quinn, Co-chairs* No report.

> Technology

Matt Grissinger reported that actions outlined in the at-risk behaviors draft would apply to all practice areas. Risk managers and healthcare professionals constitute the main audience for the paper but information should be expanded to the web site to educate organizational leadership. The challenge is to have people acknowledge that risky behavior may lead to errors and to educate people to recognize risky behavior. Health care providers must also consider the patient's language and health literacy to help prevent errors.

Action Item: Matt Grissinger will develop version 4 of the At-Risk Behaviors draft and forward it to the Secretariat for distribution to the Council for review. A check list for implementation or guidelines will be added.

➤ Practice Related Issues – Carla Saxton, Chair

Medicare Part D is impacting medication errors. Questions on formulary switching were sent to surveyors and medical directors for reactions. Medications can be prescribed inappropriately because physicians have little training in drugs; however, no professional liability claims have been made to date. Switching is a big issue for physicians and AMA already has established a coalition to look into such issues as to whether or not formularies are appropriate in out-patient settings. After discussion regarding sending some form of document to CMS, the Council decided to continue to monitor the issue.

➤ Promoting, Monitoring & Evaluating — *Deborah Nadzam*, *Chair* Draft 2 of the Mission Statement was unanimously accepted by the Council.

Recommendations Discussed:

- o Reduce Medication Errors in Non-Health Care Settings recommendations are still relevant and no changes are needed at this time
- o Standardizing Bar Coding on Medication Packaging
- o Labeling and Packaging to Regulators and Standards Setters
- o Labeling and Packaging to Industry suggestion was made to provide unit dosing on labels of all drug products
- o Labeling and Packaging to Health Care Providers
- o Labeling and Packaging to Health Care Organizations

Action Item: Diane Cousins and Carol Holquist will confer for specific comments regarding regulators and standards setters.

Action Item: Members are to review the proposed changes to the six recommendations and send comments to Joe Cranston no later than September 1.

As he would be unable to attend Day 2 of the meeting, Mick Murray, Chair of USP's Safe Medication Use (SMU) Expert Committee, updated the Council about the Committee's activities:

- USP's Center for the Advancement of Patient Safety is providing data about problems with enteral feeding devices to the Expert Committee. The Committee is working with Jay Crowley at FDA on this issue.
- o The SMU Expert Committee has approximately 15 action items that it is addressing and looks forward to working with the Council.

The meeting was adjourned at 5:04 p.m.

June 21, 2006

Council Delegates Present:

Linda Hanold, Chair (JCAHO) Kasey Thompson (ASHP) Mike Datena (DoD) Carla Saxton, Vice Chair (ASCP) Diane Cousins, Secretary (USP) Carol Holquist (FDA) Lee Rucker (AARP) Sal Peritore (GPhA) Lyn Bentley (AHCA) Matt Grissinger (ISMP) Joe Cranston (AMA) Polly Johnson (NCSBN) Rita Munley Gallagher (ANA) Ray Bullman (NCPIE) Ellen Quinn (ASHRM) Deborah Nadzam

Alternates attending as representatives of their organizations:

Jon May (NABP)

Rosemary Cook (PhRMA)

Alternates attending with their delegates:

Mary Gross (FDA)

Kristin Hellquist (NCSBN)

Shawn Becker (USP)

Organizations/Members not represented:

AHA NPSF APhA VA

HDMA David Kotzin

Michael Murray (Chair, USP Safe Medication Use Expert Committee)

Observers:

Denise Torrey (FDA)

Esin Kadiev (ASHO Summer Intern

Rod Hicks (USP)

Ms. Hanold reconvened the meeting at 8:45 a.m. The summary for the February meeting was unanimously approved with changes. Ms. Hanold suggested posting the At-Risk Behavior paper on the website. She also offered to submit the paper as is to JCAHO's Benchmark Journal to see if the Journal would be interested in publishing it. The article would reference the Council web site.

Action Item: Linda Hanold will submit existing At-Risk Behaviors materials to JCAHO's Benchmark Journal to determine if there is any interest in publishing it.

Unfinished Business

The Council reviewed changes to the Mission Statement and Strategies. What were formerly named Objectives will now be know as Strategies. Another version will be drafted for review by the Strategic Planning Subcommittee.

Action Item: Deb Nadzam will redraft the Mission Statement and Strategies for review by the Strategic Planning Subcommittee.

Drug Suffix Workshop Recommendations

The Council reviewed the recommendations presented by the subgroup. A question was raised as to the definition of "drug suffix" and whether there were any issues with the definition. The transcript of the Workshop will be checked to see if any changes were made during the session. The consensus at the Workshop was that suffixes in and of themselves are not an issue, Rather, it has been the misuse and misinterpretation of suffixes that have caused confusion among health care providers and patients, leading to a need to raise the level of education and awareness of suffixes to avoid future errors. It was suggested that there are three levels and goals for Council consideration:

- 1. Should there be suffixes of any kind?
- 2. Should suffixes be standardized? (long term goal)
- 3. Are there any recommendations that the Council could make now to minimize errors? (short term goal)

The following were put forward as steps the Council could take to educate people about problems involving drugs with suffixes:

- 1. Have JCAHO issue a Sentinel Event Alert about suffixes and the problems involved with their usage
- 2. Educate health care professionals as to what questions to ask to avoid mix-ups and misuse because of suffixes
- 3. Increase patient awareness by alerting them to ask what the suffixes mean
- 4. Have FDA sponsor a stakeholder meeting on suffixes, which may ultimately lead to regulatory action
- 5. Establish standards/guidelines for the safe use of medications containing suffixes
- 6. Establish a pilot program with one drug containing a suffix and track it through the healthcare continuum
- 7. Compile a glossary of prescription drug names and suffixes plus definitions

Action Item: Linda Hanold will draft a preliminary version of easy-to-achieve recommendations for the use of drug suffixes.

Action Item: Diane Cousins will contact Red Book to see if they will work with the Council on compiling a drug list for the glossary.

Action Item: Matt Grissinger will assess the drug list from the Workshop and build on it to compile the glossary.

Action Item: Presentations from the Drug Suffix Workshop will be posted on the NCC MERP web site.

The white paper needs to developed and disseminated before it becomes outdated and irrelevant. The transcript of the Workshop will be divided and sent to members of the transcription team, who will summarize specific sections and return the summaries to the Secretariat within 30 days of receipt.

Action Item: The transcript from the Drug Suffixes Workshop will be sectioned and sent to Carla Saxton, Mary Gross, Joe Cranston, Lee Rucker, Deborah Nadzam, Kasey Thompson, Linda Hanold, and Shawn Becker to be summarized and returned to the Secretariat within 30 days of receipt.

Action Item: Linda Hanold will draft a press release about the Workshop for Council review at the October meeting.

Recommendations will be posted on the NCC MERP web site when they are finalized and approved by the Council.

Matt Grissinger presented a draft of a survey that was developed three years ago from a prior suffix survey done by ISMP's Med-E.R.R.S. program. The questions were primarily pharmacy-related, leading to a proposal to have nursing and medical input to expand the survey. The Council decided to include a demographic information section and to disseminate the survey by utilizing either Survey Monkey or Zoomerang, depending on costs.

Action Item: Matt Grissinger will redraft the survey to include sections applicable to medicine and nursing and e-mail it to the Council for review.

Recycling of Medications in Nursing Homes

Carla Saxton provided background for this issue. Although other organizations have agendas regarding the recycling of medications, there is still a need for fact-finding regarding the use of unused pharmaceuticals and their disposal. Lyn Bentley stated that CMS policy is that facilities must recycle medications if they receive Medicaid money. Ms. Saxton said that a policy statement from the Council would be very powerful and useful to support other members' efforts and policies. She volunteered to be the lead in collecting information from member organizations and making a formal presentation to the Council.

Action Item: Lyn Bentley will forward the CMS letter to Diane Cousins.

Action Item: AHCA, APhA, ASHP, and NABP will check their policies for recycling medications and forward information to the Vice Chair.

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

AARP (Lee Rucker) – AARP has consolidated all of its resources focusing on the safe, appropriate use of medicines at one place on its website: http://www.aarp.org/usingmeds/. Also, AARP's largest annual exposition, "Life @ 50," will feature its Visiting Scholar Bill Thomas, M.D., who was just named by U.S. News as one of "America's Best Leaders." (See the June 19, 2006 edition; article on Dr. Thomas is at: http://www.usnews.com/usnews/biztech/articles/060619/19leader.htm. Dr. Thomas, founder of the "Eden Alternative" for nursing home care, is AARP's official spokesman on safe medicine use and medication management. The "Life @ 50" event will be Oct. 26-28 in Anaheim, CA. The SOS-Rx Coalition, which focuses on improving senior's medication use in outpatient settings, launched a consumer awareness campaign on the safe use of anticoagulant medicines on May 30. The campaign's new website is: http://www.mybloodthinner.org/. Many NCC MERP members are already involved in the SOS-Rx Coalition.

AMA (Joe Cranston) – AMA continues to collaborate with the Institute for Healthcare Improvement (IHI) on its 100,000 lives campaign. It is also addressing the issue of medicine reconciliation. AMA held a CME session at its Annual Meeting on new professional labeling and drug risk communication. Robert Temple, MD, and Scott Gottlieb, MD, of FDA were presenters. AMA's ethics area has received a grant to develop a sound prescribing curriculum. AMA has formed a coalition and is working with AHIP and CMS on Medicare Part D issues (e.g., formularies).

NCPIE (Ray Bullman) - On Monday, June 19, the National Council on Patient Information and Education (NCPIE) participated with the FDA in the launch of FDA's new nonprescription medicine education campaign, "Medicines in My Home," (MIMH). NCPIE is pleased to be a partner on the program and will be working with the agency to build awareness about the program, which is a one class period program targeting 6th-8th grade middle school students. All the materials needed to present the 45-minute program, including downloadable student handouts for MIMH, are available on the Internet at www.fda.gov/medsinmyhome/. NCPIE is also partnering with the University of Tennessee Cooperative Extension Service and the University of Tennessee College of Pharmacy on "Be MedWise Tennessee." This state-wide outreach and educational program uses key messages licensed from NCPIE's nationally focused Be MedWise campaign and delivered at the community level by cooperative extension agents, pharmacists, and pharmacy students throughout Tennessee's 95 counties. On June 7, NCPIE was informed that the FDA's final guidance on Useful Consumer Medicine Information (CMI), was days from publication. NCPIE will host an allstakeholders' meeting upon publication of the final guidance to provide an opportunity for the agency to present the document and respond to stakeholders' questions. (As of July 5, the document is still not publicly available).

NABP (**Jon May**) – NABP and the State Boards of Pharmacy are committed to promoting and implementing regulatory initiatives for improving patient safety and minimizing the incidence of medication errors. NABP's mission is to assist the state boards by developing, implementing, and enforcing uniform standards for the purpose of protecting the public health under the direction of the state boards. To that end,

- NABP convened the Task Force on Transition of Pharmacy Regulation from the Dispensing Process to Outcomes in 2002
- In 2004 the Medication Errors Task Force developed continuous quality improvement (CQI) programs and encouraged state boards to require pharmacies to document and report medication error incidents. To date, 15 states mandate CQI programs in various pharmacy settings.
- A partnership with ISMP enables NABP to share medication error incidents via The National Pharmacy Compliance News section of the state boards of pharmacy newsletters.
- In collaboration with organizations, such as AACP, AACN, and AAMC, NABP has worked to revise curricula to incorporate patient safety and error reduction.
- In the area of e-prescribing, expert testimony was provided to the National Committee on Vital and Health Statistics.

NABP continues to work with state boards to assess, develop, and implement best practices/non-punitive regulations and enforcement actions that are aimed at promoting patient safety and medication error reduction.

NCSBN (**Polly Johnson**) – On July 7, NCSBN is hosting a Summit on Medication Aides in Chicago. People can sign up on the web page www.ncsbn.org under Events. The summit will

focus on unlicensed personnel's role in medication administration, delegation of supervision by licensed nurses, and public protection. A medication aide training curriculum is under development by NCSBN at the request of its member boards. The next step will consist of a uniform competency test for medication aides. Current policy discussions related to medication administration in the school setting by school personnel other than nurses are being held by member boards and professional organizations, including ANA and school nurse associations. Many state boards participated in the ISMP webcast related to Just Culture. The Minnesota Alliance for Patient Safety (MAPS) program was featured. The annual meeting of NCSBN will be held August 1-4 in Salt Lake City. Major issues to be address include bylaws revision related to structures and governance changes.

USP (**Diane Cousins**) – On June 16 USP held a Compounding Stakeholder Forum. A question arose as to whether patients should be informed that medications were compounded. The organizations present were in favor of this. Ms. Cousins asked if this was an issue that the Council should consider for future work. A Stakeholder Forum for Safe Medication Practices is scheduled for October 11, 2006. USP has expanded its data analysis of medication errors reported to MEDMARX[®] for the pharmaceutical industry. Increasingly, prior to launching new products, pharmaceutical companies are inquiring about errors. FDA has been receiving error analysis for some time.

The following member organizations provided oral reports to the Council:

ANA FDA
ASCP ISMP
ASHP JCAHO
ASHRM PhRMA

DoD Deborah Nadzam

GPhA (**Sal Peritore**) – Nothing to report.

Evolving Role of the Council

The Chair reviewed the accomplishments of the Council and urged it to maintain an ongoing presence through publications, presentations, work products, and participation in national activities in order to remain a recognized and integral player in the medication error reporting and prevention arena. Toward that end the Council needs to articulate short-and long-term strategic plans that include objectives for projects and areas of investigation and monitoring. One future project could be assisting in the development of in-house reporting programs. There has been interest in other countries in being part of the Council or setting up their own councils and this could present opportunities for the Council to expand its influence and work products.

Linda Hanold thanked the Council for the privilege and honor of serving as Chair for the past two year. Diane Cousins thanked the Chair for her time and service, noting that the Council has never before accomplished as much in a two-year period.

The meeting was adjourned at 1:52 p.m.