Wednesday, July 13, 2011 10:00 a.m. – 4:00 p.m. Briggs & Parker, Marshall/Riley Room Draft Minutes

Goals and Anticipated Outcomes:

- 1. Request for Chair and Vice Chair nominations
- 2. Discussion of Criminalization Statement outreach
- 3. Revisit definition of Medication Error
- 4. Subcommittee reports and action items

Council members present:

Bona Beniamin (ASHP), Chair Rita Munley Gallagher, Vice-Chair Shawn Becker (USP), Secretary N. Lee Rucker (AARP) Jean Krause (ACPF) - by phone Barry Dickinson (AMA) Donald Martin (APSF) - by phone Deborah Davidson (NCPIE) Ann Gaffev (ASHRM) Carol Holquist, (FDA) - by phone Gordon Johnson (GPhA) Frank Federico (IHI) Manisha Shah (NPSF) Michael Gaunt (ISMP) Crystal A. Riley (TJC) - by phone Rita L. Brueckner (VA) Tom Clark (ASCP) **Diane Cousins**

Alternates attending as representatives of their organizations:

Marcie Bough (APhA) Yvette Bolla (ANA) Tara Modisett (NASPA)

Deborah Nadzam

Organizations not represented:

American Association of Physician Assistants
American Geriatrics Society
Department of Defense
Generic Pharmaceutical Association
Pharmaceutical Research and Manufactures of America
Society of Hospital Medicine

Observers:

Stephanie Fullmer (NCSBN) Diana Singh (AHA) Arnie Clayman (ASCP) Donna Goldberg (USP) Nobuo Uemura (USP)

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- 1. Opening, Procedural, and Administrative Matters Bona Benjamin
 - Ms. Benjamin called the meeting to order at 10:10 a.m.
 - Ms. Benjamin asked the delegates, alternates, and observers to introduce themselves.
 - She then asked if Council members had reviewed the February 2011 meeting summary and if they had any changes. Hearing no suggested changes, approval of the summary was moved by Dr. Gallagher and seconded. Council members approved the summary by unanimous consent.
 - Ms. Benjamin reviewed the meeting agenda and asked for any corrections or additions.
 Dr. Gallagher added a correction, which was to note the agreement from the Council to
 address any conflicts of interest prior to the meeting based on the agenda topics. Ms.
 Becker moved for approval of the agenda and the motion was seconded. Council
 members approved the agenda by unanimous consent.
 - Council members were asked to disclose any conflict of interest regarding the meeting content. None was noted.

2. Secretariat's Report — Shawn Becker

- Ms. Becker distributed the current NCC-MERP roster and asked for all corrections or changes. Edits were collected.
- Nominations will be sought for a new Council Chair and Vice-Chair, the new elections
 will be held in September. Ms. Becker asked all to review the list of qualifications on the
 website and respond when the call for candidates was sent out.
- Ms. Becker noted that the ACP Foundation membership will be up for renewal at the
 October meeting. Jean Krause asked if a notice could be sent out to that effect. Ms.
 Becker indicated that it was routine to notify the organization by e-mail on all renewals.
- Ms. Becker reported that Beth Feldpush has left her employment at AHA and will no longer be a NCC-MERP delegate. Diana Singh was sent to represent AHA at this meeting.

Current Issue – Taxonomy Request

Copyright issues:

- Ms. Becker asked the Council's assistance on how to address request for use of the Council's taxonomy. She shared a recent request that had not yet been answered. The request came from Johns Hopkins Hospital. Request asked for total use of the taxonomy with the ability to change at their discretion.
- A subcommittee was formed to consider requests and other issues related to our taxonomy. The members include: Diane Cousins (Chair), Rita Munley Gallagher, Shawn Becker, Michael Gaunt, Carol Holquist, Tara Modisett, and Jean Kraus.
- One of the first duties of the subcommittee will be to standardize copyright language for those who request the use of NCC-MERP taxonomy.
- Ms. Cousins added that they should also develop additional rules, so that the Council
 can remain consistent with response and still be able to address various situations or
 requests.

Action Item: Arrange for a subcommittee teleconference prior to Oct. 27 meeting. Members to include: Diane Cousins (Chair), Rita Munley Gallagher, Shawn Becker, Michael Gaunt, Carol Holquist, Tara Modisett, and Jean Kraus.

3. Drug Shortages — Bona Benjamin

- Ms. Benjamin gave a slide presentation on drug shortages and the problems that are
 occurring. Some main issues concern shortages on medically necessary drugs, such
 as electrolytes and oncology medications, along with medications that have no generic
 equivalents.
- Adverse patient outcomes are occurring. ISMP issued a safety alert on this topic last fall.
- Ms. Benjamin mentioned a well-written book on adulterated drugs by Katherine Eban, Dangerous Doses: How Counterfeiters Are Contaminating America's Drug Supply.
- The ASHP has offered recommendations on how to mitigate the shortages (posted at: http://www.ashp.org/shortages).
- A Council member informed others of the increasing amount of media that has been given to the drug shortage awareness, e.g., stories on CNBC, in the Wall Street Journal and the NY Times.
- Ms. Holquist informed the Council that FDA CDER will be holding a public workshop on the drug shortages problem, September 26 at FDA Headquarters in Silver Spring, MD.
- Council members requested that the Council to be more involved with solutions to these issues. Possible suggestions may include: a mass message from the Council against the hoarding and or wasting of expired drugs; encourage an organized approach to sharing/borrowing drugs to better meet supply and demand; allocation protocols for those most in need.
- **4.** Revisit the NCC-MERP definition of Medication Error in relation to Harm vs. Error Current climate relevant to the MERP definition was addressed by Dr. Gallagher and Ms. Cousins provided the philosophy of the original Council membership.
 - Dr. Gallagher started the discussion on medication error and harm vs. error, and said that sometimes the NCC MERP definition is interpreted differently depending on the setting. Potentially negative connotation and consequences to medication errors.
 - Medication error was originally selected years ago by the then Council membership.
 The name: medication error reporting and prevention is a name that has become a standard and is used by healthcare practitioners and media throughout the nation.
 - Ms. Brueckner told the Council that the VA does not use the word preventable or error in its definition of a patient-related unusual occurrence. Preventable implies the error could be intentional and as such could be avoided 100% of the time. The VA uses the term adverse event and such events could be untoward, iatrogenic, or unintended. An adverse event as defined by the VA may or may not have resulted in patient harm.
 - Another member indicated that CMS uses standards enforceable by state law to define medication error.
 - Mr. Federico noted that IHI uses the Council's definition for medication error, except that the definition of harm is more contentious.
 - There was a general agreement from the Council members that no change in the definition was needed at this time. The Council will continue to monitor concerns expressed.

5. Criminalization Statement — Bona Benjamin

Discuss concerns raised by NABP during the balloting process.

The NABP suggested replacing "medication safety" with "patient safety," and asked that
a footnote be added to clarify the scope of the statement, i.e., the statement should be
clear that it covers more than medication errors and if covering more than medication

errors then why is the definition of medication error included.

- Ms. Becker noted that the criminalization statement was approved and posted on the NCC MERP website. Dr. Gallagher moved and it was seconded to reevaluate the document for possible revisions. The vote was approved by majority with one abstention.
- A subcommittee for possible revisions will be formed to include: Deborah Nadzam, Ann Gaffney, and Scotti Russell. A chair will be chosen once the subcommittee convenes.
- Ms. Benjamin reminded all that a revision was not meant as a new statement; that the
 approved statement would remain, and that the revision was only to add clarity and
 remove any confusion.
- The subcommittee will report back no later than the February 2012 meeting.

Action Items: Subcommittee will convene to address possible revisions to Criminalization Statement. Members include: Deborah Nadzam, Ann Gaffey, and Scotti Russell.

6. Subcommittee/Task Force

- a. Medication Management Report Frank Federico
- Mr. Federico described the activities of the subcommittee on Medication Management and indicated that there is also a wider on-going project among other groups and asked the Council if we should consider partnering others. He said whatever is decided there should be an agreement to compliment each other's work.
- The Council questioned whether we have enough funding and workforce to make a contribution to this on-going work effort. The Council decided the best way to continue was to monitor the overall efforts by others that support patient safety.
- Mr. Federico asked if the council would like to receive a report from the Pharmacy Quality Alliance (PQA) at the next Council meeting.
- Mr. Federico sought input on whether to partner with The Joint Commission after their offer to work with the Council at the January meeting.
- Council members agreed to invite PQA to give the Council a report on its work in this
 area at the next meeting.
- Mr. Federico made a motion to take the Metrics Project off the NCC MERP list of projects and monitor other organizations efforts. Motion carried unanimously.

Action Item: Mr. Federico to invite PQA to the next Council meeting.

b. AHRQ Crosswalk of Measurement with NCC MERP Taxonomy — Diane Cousins

- Ms. Cousins described the NCC MERP taxonomy. She said any change to the current taxonomy and classification should be done carefully.
- She spoke about the current similarities between the Council's taxonomy and the taxonomy from AHRQ, saying that both had common formats. She described the crosswalk of both measurements.

7. Member Updates

- A Council member expressed concern over the "quick promise" ads of pharmacy refills and the increased possibility of error in these situations.
- Members asked if the Council should be looking to develop medication management guidance for patients currently being cared for by remote or robotic systems. A new subcommittee was suggested to tackle the issue of quick refill promises and also

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- address developing guidance for remote/robotic medication delivery. Committee members volunteered: Tom Clark and Michael Gaunt.
- Ms. Becker stated that a summary of the July 13 Council meeting will be posted to the NCC-MERP website.
- Ms. Benjamin said that she hopes the new subcommittees will be prepared to give either an initial or a complete report at the October 27 meeting.
- The next Council meeting is a webinar on October 27, 2011 from 1:00 p.m. 4:00 p.m. EDT. A motion was made by Dr. Gallagher and seconded that future meetings will be held quarterly in January, April, July, and October with only one face-to-face meeting in July. The motion was approved unanimously.

Action Item: Form a subcommittee to address quick refill promise ads. Members include Tom Clark and Michael Gaunt.

Meeting adjourned at 2:50 p.m.