# Mems 2.0 Orientation

## Meeting Information

| | |
|---|---|
| **Date:** | August 9, 10 AM EDT<br>August 10, 12 PM EDT<br>August 13, 3 PM EDT |
| **Time:** | See above |
| **Call in Number** | USA +1-203-418-3123 |
| **Passcode** | 1599520 |

**Orientation Participants:** Justin Alexander (RPC), Doris Auth (FDA), Pamela Ball (AOA), Mark Baczkowski (RPC),Rod Campbell (University of Pennsylvania), Kathy Chappell (ANCC,) Jemma Contreras (Campbell Alliance) ,Stephanie Cordato (Campbell Alliance) ,Tony D'Ambrosio (RPC),Barry Dickinson (AMA), Jennifer Dunleavy (ACCME), Lisa Fennell (ARBO), Susie Flynn (AAPM), Scott Hershman (AHME), Ed Kennedy (ACCME), Myoung Kim (RPC), Linda Kitlinski (RPC), Bob Kristofco (RPC), Anjam Malkana (Campbell Alliance), Sue McGuiness (RPC), Stephanie Mercado (AAPMR), Andrea Morgan (ACCME), Sherice Mills (RPC), Anshu Sawhney (Campbell Alliance), Lorraine Spenser (Johns Hopkins University), John Sweeney (ACCME), Suzette Tomaska (RPC), John West (Campbell Alliance).

**NOTE: This document summarizes the proceedings of orientation calls held August 9. 10, and 13, 2012.**

## Agenda Items

**1 Introductions**

Valerie asked call participants to introduce themselves.

- Justin Alexander, Director of R&D IT at Purdue Pharmaceutical. He is on the EMS Program Companies (RPC ) Technology subteam.
- Doris Auth, Team Manager, Risk Management Assessment Review at FDA.
- Pamela Ball, Assistant director of CME at the American osteopathic Association (AOA)
- Mark Baczkowski, Mylan, Metrics subteam of the RPC
- Rod Campbell, Data and Systems Coordinator, University of Pennsylvania
- Kathy Chappell, Director of Educatio, American Nurses Credentialing Center (ANCC)
- Jemma Contreras Campbell Alliance, Project Management Office for the REMs project
- Stephanie Cordato, Consultant, Campbell Alliance, Project Management Office for the REMs project
- Tony D'Ambrosio, Director of IT at Janssen Pharmaceuticals, RPC Technology subteam
- Barry Dickinson, Director of Science and Biotechnology, AMA
- Jennifer Dunleavy, Director of Operations, ACCME
- Lisa Fennell, Executive Director, Association of regulatory Boards of Optometry (ARBO)
- Susie Flynn, Director of Education, American Academy of Pain Medicine (AAPM)
- Scott Hershman, Medical Director, Office of Continuous Professional Development, ACA Health One, Association for Hospital Medical Education (AHME)
- Ed Kennedy, Manager of Information Technology, ACCME
- Myoung Kim, Medical Affairs, Janssen Pharmaceuticals, Metrics subteam of RPC.
- Linda Kitlinski , Senior Director at Endo Pharmaceuticals and Chair of the RPC CE subteam
- Bob Kristofco, Pfizer Medical Education, RPC CE subteam
- Anjam Malkana Campbell Alliance, Project Management Office for the REMs project
- Sue McGuiness, Medical Education, Teva , RPC CE subteam
- Stephanie Mercado, Associate Executive Director, American Academy of Physical Medicine and Rehabilitation (AAPMR)
- Andrea Morgan, coordinator of data information systems, ACCME
- Sherice Mills, Manager, Product Safety, Covidien, RPC CE subteam
- Anshu Sawhney, Senior Consultant, Campbell Alliance, Project Management Office for the REMs project
- Lorraine Spenser, IT Manager, CME, Johns Hopkins University
- John Sweeney, Manager of Data Information Systems, ACCME
- Suzette Tomaska, Associate Director of Medical Education, Purdue Pharmaceuticals,RPC CE subteam
- John West Campbell Alliance, Project Management Office for the REMs project

**2 Meet the people involved**

Valerie walked though the slides. Francis Kwakwa, Assistant Director of Data Management at Radiological Society of North America (RSNA), is the chair of the MedBiquitous Metrics Working Group. Valerie is the Deputy Director of MedBiquitous and will prepare the technical documents for the group to review and gather their requirements. Jody Poet is the Administrative manager of MedBiquitous and will provide additional support for the working group.

Many people were involved in the development of Medical Education Metrics 1.0, the standard that we will be building on. Valerie acknowledged the contributions of the contributors to that standard.

**3 Goals**

Valerie provided some background information on the impetus for the project. The FDA released a Risk Evaluation and Mitigation Strategy for Extended-Release and Long-Acting Opioids in July. The intent of the REMS is to address opioid misuse and abuse, managing the risk and maximizing the benefit of opioids. One component of the REMS is prescriber continuing education. the RPC will fund REMS CE and, working with accreditors, collect data on the scope of REMS CE.

The goals of the MedBiquitous MEMS 2.0 project are to revise the MEMS technical specification to support the exchange of ER/LA Opioid REMS educational outcomes data for the health professions and to provide assistance to the accrediting bodies and the RPC in implementing the MEMS technical specifications.

**4 Introductions to MEMS**

Valerie reviewed MEMS 1.0 to provide background. MEMS 1.0 is a standard format for CE outcomes data that allows educators to bring data together from across multiple systems. MEMS 1.0 includes:

- Report description
- Activity description
- Participant survey data (aggregate results; may include before/after comparisons)
- Knowledge assessment data (aggregate multiple choice or score data)
- Participation metrics, including credits awarded

More details on MEMS 1.0 are available at: http://bit.ly/memsfull

MEMS 2.0 will be designed to allow accreditors to collect REMS CE data from CE providers and then send it to a common educational outcomes database.

If organizations can't support XML, using an Excel template based on the XML standard is an option. The organization receiving the data must agree to receiving the data in that format. In the PARS system, the ACCME accepts data entered manually via web form, excel data, and XML.

**5 Development process**

Valerie reviewed flow charts describing the MedBiquitous standards development process. Over the next 6 months, the working group will draft a specification. The draft specification will be presented to the Standards Committee for review, and the working group will work to address any comments received. Once those comments have been addressed, MedBiquitous sends the specification to ANSI for public review. Again, the working group must work with the Standards Committee to address any comments received. Then the specification is balloted within the Standards Committee. If any comments are raised that require substantive changes, another public review is required. Otherwise, MedBiquitous finalizes the specification and sends it to ANSI for final approval as an American National Standard. It's a process that takes several months.

The process of drafting the initial specification is being accelerated. The RPC is providing financial support so that this work may proceed on an accelerated timeline, with calls occurring twice a month.

**6 Communications**

The working group will have teleconference twice a month. In addition, we will use a wiki and mailing list to facilitate communication and collaboration.

wiki: http://groups.medbiq.org/medbiq/display/MWG/Home

Mailing list: metrics@medbiq.org

To send messages to the group, use reply all or send the message directly to metrics@medbiq.org.

**7 Project Plan and Timeline**

Valerie reviewed the project plan and timeline. Our next steps are to develop use cases and analyze data requirements. Once that is complete, we will begin developing the specification. We should have a draft specification ready by December 7.

**8 Future call**

Valerie asked call participants to indicate their availability for a future call using the doodle poll linked form the agenda.

**Q&A**

Justin asked how many providers use XML vs. excel. Valerie commented that a recent survey about CE providers' use of IT (in general) revealed that many CE providers are still in fact using paper-based records/materials. Larger providers are more likely to use sophisticated IT solutions. Excel templates allow providers with less-advanced systems to participate in MedBiquitous standards.

Jennifer commented that ACCME data indicates that in 2011 70% of CE Providers used manual web entry; 25% used tab-delimited (Excel); < 5% XML. Approximately 5 providers were using XML in 2010; 10 in 2011. Those 10 are larger CE providers submitting larger amounts of data. It's a small count but the use of XML and other IT tools is increasing.

Justin asked how novel this approach was to MedBiquitous and what rules of the road industry should adhere to. Valerie replied that MedBiquitous has engaged in other accelerated standards development projects funded by the Association of American Medical Colleges and the National Board of Medical Examiners. MedBiquitous' ANSI accreditation requires that MedBiquitous remain transparent and open to any materially affected party, and MedBiquitous adheres to that accredited process for all standards projects, including accelerated ones. The ACCME and other accreditors have standards of commercial support that ensure the independence of CE providers in creating content. Industry should be mindful of those standards of commercial support when interacting with CE providers.

Stephanie M. asked where the compiled data will be housed. Sherice replied that the RPC is contracting with a vendor to house the data. Stephanie M. asked about the relationship to the IWG. Sherice explained that the IWG is now the RPC. The RPC will analyze data and send it to the FDA.

Sherice asked if the current standard can show where people have difficulties. Valerie offered to look at the current specification in more detail. She commented that there would need to be agreement form the accreditors on the willingness to collect that data in a consistent manner.

## Decisions

## Action Items