2018-03-20

Meeting Information

Date:	March 20, 2018
Time:	5 PM EDT/4 PM CDT/3 PM MDT/2 PM PDT

Attending: Francis Kwakwa, Chair; Doris Auth, Pamela Bennett, Caitlyn Briggs, Prasad Chodavarapu, Jennifer Dunleavy, James Fiore, Jason Haag, Illana Hardesty, Rima Izem, Cynthia Kear, Joanna Krause, Jack Kues, Rahul Natarajan, Linda Noa, Amy Opalek, Kate Regnier, Sheila Robertson, Amy Smith, Valerie Smothers, Marsha Stanton, Amy Tan, Mark Terrell, Dimitra Travlos, Julie White, Runa,

Valerie introduced Amy Opalek and Prasad Chodavarapu, the chair and editor of the Professional Profile working group. She asked them to participate in call due to the shift in focus received from the FDA. Their input with the technical architecture will help. (Note: James Fiore, chair of the Activity Report Working Group was also listening to the call.)

1 Review minutes

The minutes were approved as submitted.

2 Discuss questions related to the implementation of learner level data.

What specific needs/questions would the learner level data enable FDA to address?

Rima explained the goal for receiving learner data is two-fold. 1) Assess the reach of the program and answer questions like who is volunteering to take training, to identify gaps in the reach of the program 2) Create a frame of reference for other studies. They are rewriting REMS evaluation goals, and granular data will allow for cross tabulation. Doris confirmed data sets would be de-identified.

Will data sent to accreditors be de-identified?

Valerie explained ways de-identification can work. CE providers can send de-identified data to the accreditor, or CE providers can send identified data and have the accreditor de-identify the data on their behalf. She provided a brief background on REMS activities, maintenance of certification, CE providers send data to ACCME and then to certifying boards. Cynthia commented that sending identified data could have a negative impact on engagement. Several in the group agreed. Cynthia asked what the requirements would be for grantees. Kate explained that currently grantees report aggregate numbers per activity to the accreditor. This change would require providers to report learner level data to the accreditor. The ACCM he currently collects learner level data in PARS to support maintenance of certification.

Dimitra noted that the REMS data they receive is a separate process; they never see identifiable data. Francis asked if there is a lot of retooling to collect this data. Kate thought there would be a significant amount of work changing the current way REMS data is collected. Dimitra commented not all accreditors would have system in place to handle this change. It will take time and resources. Cynthia agreed. Julie asked if it would be helpful to have a so that the FDA may determine whether learner level data will meet their needs and provide the desired insights. Cynthia suggested having a pilot using MedScape. Doris acknowledged that systems would take time to build. This data would only be collected prospectively; decisions would not be retroactive. Francis asked if the rollout would be staggered with the change would take place all at once. Doris responded that the FDA does not want to mix of different types of data.

Will data sent to the RPC be de-identified?

The group agreed data sent the RPC would be de-identified.

What if the FDA requires REMS CE? How would that learner-identified data be reported?

Valerie asked if the FDA requires REMS CE. Doris added that is beyond their control, mandatory verses not mandatory. Cynthia asked Doris how learners prove they have taken a course. Doris suggested tabling that conversation for later. Dimitra suggested tagging on to the mandatory REMS education system. Doris agreed.

What if some learners want their identified data used for a regulatory purpose, like Maintenance of Certification, or Licensure? and others don't? How would providers and accreditors manage that?

Illana explained if they want data used for regulatory purposes it is sent off electronically; that is a different issue than delivering de-identified data to the FDA. Kate expressed concern about reporting that same learner data twice, once identified and once de-identified. Is there a simple way to report learner data only once? Doris asked if you could subtract out the ones that received credit for MOC. Valerie thought that would get complicated. Cynthia mentioned providers would send identifiable information then your system would be responsible for de-identifying. Kate suggested coming up with a technical solution.

How will we uniquely identify learners if that is a requirement?

Valerie suggested waiting until we find out if we need to.

When should CE providers start collecting this new data?

Valerie suggested letting CE providers determine that and give an estimate on the time required to collect data and the time required for accreditors to be ready to receive it. Cynthia noted there might be budget implications. Valerie will send a note out asking everyone to get back to her within three weeks regarding how much time they think it will take to retool their systems.

When do accreditor systems need to be ready to receive this data?

3 Discuss requirements and how they map to existing specifications

Activity Report

Professional profile

Valerie explained that there are three MedBiquitous specifications that could be relevant for exchanging this data.

- The Metrics specification provides aggregate data about an activity and its relationship to REMS.
- The Activity Report standard provides a record of the learner's participation in a CE or maintenance of certification activity.
- The professional profile standard provides descriptive information about a learners credentials.

There is a lot to build on, but nothing is a perfect fit. The linked document shows individual requirements from the FDA and how they map to existing standards. She suggested the co-chairs of the two groups meet to come up with a plan. Valerie will rely on Prasad and Amy's guidance. Amy commented it was good to listen and get an overview. Francis confirmed next steps is to schedule a call for working group leaders to hash out the architecture and then bring it back to the various working groups and come up with a strategy to vet it.

Francis asked Valerie about a timeline. Valerie suggested having the group get in touch by April 20. Doris agreed.

Action Items

- Providers and accreditors will get back to Valerie within three weeks regarding how long they think it will take to retool their systems.
- MedBiquitous staff and co-chairs will work together to come up with a proposed architecture.

Decisions