2017-05-03

Meeting Information

Date:	May 3, 2017
Time:	2 PM EDT/1 PM CDT/12 PM MDT/11 AM PDT

Attending: Francis Kwakwa, Chair; Danielle Atzeni, Caitlin Briggs, Leslie Christy, Igor Cerny, Somya Dunn, Bradley Hamilton, Linda Kitlinski, Joanna Krause, Tom McKeithen, Kate Regnier, Valerie Smothers, Marsha Stanton, Amy Tan, Dimitra Travlos and Mark Tyrrell

Agenda Items

1 Review minutes

The minutes were accepted as submitted.

2 Review revised definitions

Francis discussed the FDA expanding REMS to Immediate Release Opioids and the need to change definitions and collect more data. Valerie added that the group discussed revising definitions to include individuals prescribing under institutional DEA registration. In addition, the group discussed providing data on specialty and geographic regions. Marsha noted they do not have a firm date for IR inclusion but anticipate later this year. The FDA is meeting next week. Igor encouraged attending and mentioned Doris hoped to discuss the blueprint. Marsha will send registration link to Valerie to circulate to the group. Kate mentioned Norm Kahn is holding a Conjoint Committee Data Group meeting on July 7 to discuss a response.

Valerie explained the deprecation process for the old definitions. The old definitions are necessary for historical purposes, but the group should indicate a date after which they shouldn't be used. Kate indicated a change in PARS field reporting is required and asked about data collection. Valerie noted that requires changes to the survey forms. A discussion followed about a natural cutting point. Cynthia wanted to talk with Tom from the vantage point of their own data base management. Tom had two considerations: 1) pre-printed forms would need changed and 2) waiting for any forthcoming additional changes from the FDA to make all the changes in one fell swoop. Data base changes can be made in a month. Joanna confirmed BU could make changes quickly.

Francis asked Igor what the FDA's preference to depreciate definitions? Igor deferred to the working group but preferred sooner than later. Kate expressed concern regarding cutover date when registrations have already started. Francis suggested sending a survey to providers asking when activities are complete to determine cutover date.

3 Review proposed modifications to guidelines, specs, and schema

Valerie noted that on the last call we discussed collecting specialty data, years in practice, and primary practice region, but it wasn't clear which category of learners should be broken down by specialty and region. We are providing guidance for collecting prescribers, participants successfully completing, schedule 2 or 3 clinicians successfully completing, prescribers successfully completing by profession, and in the past we provided guidance for prescribers successfully completing by practice type. Kate recommended determining what information the FDA wants about an individual. Igor mentioned it would help them determine who has taken the training, focus on what areas are under-represented, and find ways to improve things.

Mark noted some activities lump non-physicians; most CE providers do not get that granular. Cynthia added live activities are targeted to members, not a lot of others attend. She questioned whether the list of specialties needed to be presented in such situations. Francis recommended presenting the same list of specialties across the board on all activities.

4 CORE Feedback on list of specialties

5 Updates

Marsha suggested scheduling a meeting in mid-June to discuss specialty feedback. Igor added he would provide updates as the blueprint continues edits.

Decisions

Action Items

- MedBiquitous will send out a survey to CE providers asking for their recommendation on a date to cut over to the new definitions.
- The group will continue to consider which learner categories require breakdown by specialty, years in practice, and primary practice region.