2018-01-10

Meeting Information

Date:	January 10, 2018
Time:	3 PM EST/2 PM CST/1 PM MST/12 PM PST

Attending: Francis Kwakwa, Chair; Doris Auth, Pamela Bennett, Billy ?, Caitlin Briggs, Leslie Christy, Jennifer Dunleavy, Brad Hamilton, Ilana Hardesty, Cynthia Kear, Linda Kitlinski, Joanna Krause, Tom McKeithen, Rahul Natarajan, Kate Regnier, Ronald Sanwo, Amy Smith, Valerie Smothers, Marsha Stanton, Dimitra Travlos, Mark Tyrrell, and Julie White

Agenda Items

1 Review minutes

The minutes were accepted as submitted.

2 Discuss Conjoint Committee recommendations and implications for documentation (see April 2017 (1.7) draft of the specifications and the April 2017 draft of the Implementation Guidelines)

Valerie provided a brief overview of the recommendations and the implications for MedBiquitous documentation. The first change was to the list of professions, adding two additional values for profession, registered nurse and psychologist. She noted the list was different from the current vocabulary. Their interest was to look at the entire team not just prescribers. Doris noted after looking through the recommendations, the FDA list may be slightly different. Ilana added her organization uses Advanced Practice Nurse/Nurse and Nurse Practitioner. Marsha wanted to consider Doctor of Nursing. Valerie noted the key question is what the FDA does with these recommendations. The purpose of the letter from the Conjoint Committee to the FDA is to show changes in the standard and related documentation. The final rule from the FDA REMS may be slightly different.

Kate emphasized their goal is to simplify data and address questions in follow-up surveys to compare data demographically. She asked what the FDA timeline is. Doris mentioned a meeting next week with the RPC's and accreditors. The timeline depends on the feedback from that meeting. Francis requested a copy of the survey to see what the FDA are collecting. Valerie did have an example of the vocabulary used in the survey (the list of specialties). Kate clarified that is how they made some of the recommendations. Cynthia requested the list be alphabetized to avoid bias from current rank ordering. Valerie mentioned that could be done in the specification.

Valerie continued with the second question regarding are you able to prescribe. This reflects prior discussions about moving from the term schedule_2_or_3_registered_clinician to schedule_2_or_3_clinician. Mark asked if this continues to be a valid question, given the learner might not be able to prescribe but can dispense or administer. The professions targeted has expanded. Valerie suggested waiting to see what FDA recommends. Doris emphasized they still want to collect that value but struggled with how to reach other professions.

Mark noted the revised REMS will cover schedule 2, 3, and 4. Valerie asked if the FDA was interested in individual or institutional registration. Doris confirmed both. Kate clarified we have similar ways of describing DEA registration for 2, 3, or 4 controlled substances. The ACCME would say able to prescribe controlled substances. They could be registered but prescribe under an institutional registration. Valerie added prescribers were not accurately reporting prescribing behavior. According to Boston University, 19,000 reported having a DEA license but did not answer yes to prescribing, and 7000 were unsure. Doris asked how the question was worded. Ilana sent the wording of the question used.

Francis expressed concern participants do not understand the language for individual or institutional prescribers and may benefit from a brief explanation. Kate questioned if the FDA does decide it wants both, can they prescribe under either individual or institution so we are not double counting. Doris will follow-up on that. Valerie noted whatever final ruling is we will revise our definitions posted on our website.

Valerie continued with question three, on specialties. Previously we were using three different practice areas: primary care, pain specialist and non-pain specialist. The proposed list is based off the list of specialties and practice areas used in the survey sent to clinicians, with a few additions. OBGYN, pediatrics, and hospice and palliative care were added.

Doris noted the FDA wanted to break out surgery further and wondered if there could be further drop down under surgery to include general surgery, orthopedic surgery, and other surgical specialty. Valerie noted they would code each as separate values. Doris added you can be OBGYN and not perform surgical procedures. She would like to add a question that asks do you perform surgical procedures, yes or no. Kate questioned whether that would be asked of all learners or just learners who prescribe. She was wondering how to collect data in aggregate, with a fairly complicated tree of questions. Doris clarified it is not just for prescribers.

Dimitra requested a definition of surgical procedure. Marsha added both plastics and dermatology perform in and outpatient surgeries; how would you subdivide that? Doris clarified in general they want to compare across survey participants. FDA Valerie reiterated nothing will be sliced and diced until we see FDA recommendations. She noted that the FDA receives a breakdown of prescribers by profession and by practice type currently. Doris noted there are three groups named in the REMS: prescribers, nurses and pharmacists. Valerie cautioned this dramatically expands number of data points providers provide to the accrediting body. If you provide the same breakdown for all three groups, that equates to 60 data points. Tom commented the more boxes people have to check, the more you introduce survey fatigue, and get less reliable data. Cynthia agreed.

Valerie continued with question four and five primary geographic location of practice and length of time in practice. They recommended question six be eliminated but that will depend on the FDA definition of prescriber. Kate still struggled with what providers can collect from individual learners. When a provider aggregates that data and reports it to the accreditor, if we're not collecting individual learner data, how will we retain slices of data that Valerie spoke about. Dimitra suggested obtaining a list of questions from the FDA regarding what they are looking for in this data. Doris agreed to send that.

Kate commented noticeably absent from this discussion is implementation of this. It would be helpful to have questions we are trying to answer and then figure out the level of effort to accomplish. Learner level data will better answer questions rather than aggregate. Valerie noted that learner level data would require learner level consent. Kate mentioned the ACGME collects PARS for certifying boards with the expectation the learner is giving permission to have data submitted. Linda cautioned there is a sensitivity about opioid prescribing. Francis concluded we need to hear from the FDA what they really want and then continue discussion. Doris suggested scheduling another meeting in six weeks.

3 See REMS CE Final Report

4 Open Discussion

Action Items

Doris will send a list of questions that the FDA would seek to answer through reviewing the submitted data.