2012-11-29

Meeting Information

Date:	November 30, 2012
Time:	10 AM PST/11 AM MST/12 PM CST/1 PM EST
Call in Number	USA +1-203-418-3123
Passcode	1599520

Please note: the conferencing service will ask you to enter the pound sign. Press # for pound.
To mute, press *6.

Attendees: Jack Kues, Acting Chair: Tony D'Ambrosio, Doris Auth, Pamela Ball, Mark Baczkowski, Rod Campbell, Kathy Chappell, Lisa Fennell, Susie Flynn, Edward Kennedy, Linda Kitlinski, Anjum Malkana, Stephanie Mercado, Jill Olexa, Andy Rabin, Valerie Smothers, Lorraine Spencer, John Sweeney, Dimitra Travlos, John West.

Agenda Items

1. Review minutes of last meeting

There were no additions, deletions, or corrections to the minutes. Dimitra made a motion to approve the minutes, seconded by Lorraine. The minutes were approved as submitted.

2. Discuss follow up to accreditor questions

Jack began with a discussion on the questions raised and responses received from the REMS document. The first item is how the FDA defines completion of training, and how the FDA define successful completion. Based on the document we have, there are four components to that.

Valerie suggested it might be helpful for the RPC to give a brief overview of the document's context. Linda mentioned there were multiple questions from accreditors submitted prior to the last working group call. Those questions were grouped together. The RPC went through the final REMS document and marked the appropriate citations. They sent the document to accreditors to be certain they didn't misinterpret their responses. Wednesday the RPC had a teleconference with acreditors to assure that they adequately addressed their questions. There were other questions raised to the working group that weren't within the FDA purview, so those were separated out for later discussion.

Jack asked if the document was to be published. Linda mentioned the document is being shared with the FDA to insure we are interpreting the document correctly. Jack commented that some of the responses were information educational providers would want to know. Linda replied that as soon as the RPC knows the FDA response, they can share the document more broadly.

Andy asked about the definition of prescriber. Three different definitions were provided. Would learners have to answer questions with regard to all three definitions in order to know whether to include them? Linda replied that it would not be necessary to ask multiple questions. The FDA needs to know if the group of physicians writing prescriptions are the ones participating in training. Andy suggested coming up with a standard approach. Linda asked the group what they thought was the most appropriate, keeping in mind the goal of assuring the FDA that REMS directed education is going to the right learners.

Jack asked if the learners who didn't meet the definition of prescriber would be barred from the education. Linda answered no. One point four million folks have the ability to prescribe these medications by virtue of their DEA registrations. As of 2011, 320,000 had actively written one prescription in the past year. FDA intends to make education broadly available to everyone. If you are not using this class of drugs, you probably are not going to participate in a three hour session. Jack commented that noting the targeted audience is insufficient.

Susie asked if providers are expected to identify how many of our clinicians are indeed active prescribers or identify the individual prescriber that attended one of our REMS program. Linda said it's the former. Jack commented, for those doing online activities, asking these questions and having post tests links all kinds of information together, including a provider's ability to identify individual learners. Linda replied that providers in general know the identities of people completing an activity. That information is not conveyed to accreditors or to the RPC. Lorraine noted that was true. As a provider she identifies each individual that completes the program, and they do not provide that information to the accreditor.

Lorraine asked if they could ask a single question regarding prescriber status, do you meet this definition, yes or no, and then provide a count, adding a single question to the process and single field to the specification. Stephanie agree that was not onerous as long as it's self reported. Lorraine agreed.

Mark asked about knowledge assessment. Valerie noted that the FDA defines REMS training as including assessments. We need to have a count of those prescribers that completed training meeting all four components of REMS, including assessment. We can ask providers to produce that number. Linda commented if someone didn't complete the training it would be immaterial because they wouldn't get counted. Susie asked for clarification regarding prescribers verses active prescribers; would both numbers be reported? Linda answered they are one in the same. Active prescriber is what we're gearing towards, at least one script in the past year. Jack commented that may be the one question we may need to ask. Is it general enough that no one would feel it was problematic? He suggested if anyone has questions or comments, send them along to Valerie..

3. Discuss additional data requirements (view proposed data requirements) –

Valerie explained that the data requirements document was produced based on review of the Questions Raised To MedBiquitous Working Group & Responses_document, other things accreditor's discussed on Wednesday, and also previous comments from accreditors. The data requirements outlines data points that would be captured in MEMS 2.0. REMS-compliant training should indicate if the activity meets all of the requirements: addressing the full blueprint, being subject to audit, knowledge assessment, accreditation requirement. Valerie added that we should have a way to indicate which REMS it is in relation to; that would be helpful for future REMS projects. In additional the number of prescribers successfully completing activities, not just the number of prescribers participating. Prescribers are those clinicians that have written one ER/LA opioid script in the past year.

The requirements also include Blueprint elements addressed. Many accreditors have commented that there are providers offering REMS related CE but they are not fully compliant. They want some way to track that activity. Jack commented that could open up things quite a bit. What do we want to capture? Stephanie commented that at their annual assembly they have a daylong opioid REMS session. They don't award credit per session. It's complicated if you try to capture every session addressing any component of REMS. If it's a dedicated REMS activity, that may be more feasible.

Valerie commented it could be a dedicated REMS activity, not part of larger activity that addresses the whole thing. There are accreditors that want to capture that and that would be of interest for REMS evaluation. Valerie suggested making that an optional element. Jack asked if what was needed was the ability to map content to different blueprint elements and measure the elements independently. Valerie clarified that there is an interest in associating an activity with certain parts of the blueprint.

Linda mentioned this point came up last July. They had done a survey through several of the national provider organizations. Only 1/3 of REMS CE providers indicated that they would seek industry support. The other two thirds of REMS activities would not be subject to the same criteria. If AAPM is doing something that does not cover the full blueprint, we would still want a way to describe that it didn't address the full blueprint. Some accreditors don't think that is necessary; others would like to reflect that information.

Dimitra commented that in the past accreditors had discussed distinguishing between industry supported vs non-industry supported activities . They had also discussed providers conducting individualized needs assessment and capturing the section of the REMS blueprint addressed. She was unsure as to whether a final decision on those two questions had been made. The RPC had said it's up to you. REMS activity may be split up by section. Valerie commented that with regard to the distinction between RPC-funded activities and those not receiving support from RPC, the metrics 1.0 specification does have fields for indicating commercial support for an activity and acknowledgement of commercial support. We haven't talked about having a check box for RPC supported activity.

Andy commented that if an activity only addresses part of the REMS blueprint, it would not be REMS compliant from an FDA perspective. Does FDA want to see data on those activities or only on compliant activities? Linda replied that the FDA requirement is to report on fully compliant activities. Some accreditors would like to report on activities addressing part of the blueprint; that's why it is an optional field. Stephanie commented that the reason there is a blueprint is that learners must be educated on all of it. If that is the whole point, that would be things we need to measure. Susie agreed. From a provider perspective, they want to meet and exceed the blueprint. She didn't see the value in reporting activities that address part of the blueprint. Pam agreed.

Valerie moved on to the requirements for profession and specialty. This is another one of those points where feasibility is something that has been discussed quite a bit. Profession appears to be a requirement based on REMS document we have to address. There are also fields related to audit that the ACCME proposed adding, we need to discuss that on another call in more detail.

Linda commented that the data shows almost 90% of LA Opioid prescriptions are written by primary care physicians. There is a need for understanding on the reach of REMS. They want to know who is in the audience. That is why they would like to try to capture specialty in some way. Jack commented if we divide by boards we miss quite a few. For example, pain management does not have its own board. Stephanie mentioned if you were trained as general internist or family physician, specialty is going to be difficult. We could go the check box route; if you did drop down ask them to identify the specialty they most align with. Jack asked as to whether MedBiquitous had already captured specialty information somewhere. Valerie commented that the Healthcare LOM standard released in 2008 does include a list of specialties. it includes the 24 boards of ABMS and subspecialties in Internal medicine and pediatrics, But subspecialties have changed since 2008. MedBiquitous is in the process of updating that list. She can share more information on the next call.

4. Identify next steps -

Valerie continued with information on next steps. She wanted to get RPC input with regards to the document in item 2 and the plan for that document. Linda commented they provided the document to the FDA for information purposes, however; they don't expect any feedback on that other than the FDA received it. She took those responses verbatim from the language in REMS. What we talked about here today, we're ready to move on. Valerie mentioned given that we can wait and see if we hear feedback from the FDA and revise our approach, and we can move forward with those responses and continue to work on the data requirements. She commented the next step is to come to consensus on the requirements, including the mapping to blueprint elements, and she can start to map those requirements to the existing standard so we can see where the gaps are. She suggested if anyone had other thoughts, concerns, or questions, put the comment on the wiki or send an email to the group.

5. Open discussion

Decisions

The term prescriber will refer to those clinicians who have prescribed an ER/LA opioid in the past year.

Action Items

- Valerie will share information on the recommended values for specialty from Healthcare LOM.
- Valerie will map data requirements to the current specification and develop proposals for any gaps.