

# 2017-03-07

## Meeting Information

<b>Date:</b>	March 7, 2017
<b>Time:</b>	11 AM PST/12 PM MST/1 PM CST/2 PM EST

Attending: Francis Kwakwa, Chair; Doris Auth, Caitlyn Briggs, Jennifer Dunleavy, Ilana Hardesty, Cynthia Kear, Linda Kitlinski, Kyle Klassen, Joanna Krause, Valerie Smothers, Amy Tan, Dimitra Travlos, Mark Tyrrell, Julie White, and Rebecca Walker, Danielle ? (AAFP), Kim ? (FDA)

## Agenda Items

### 1 Review [minutes](#)

The minutes were accepted as submitted.

### 2 Discuss [potential expansion in scope for REMS](#)

Doris provided a brief overview on the changes discussed at the January 25 FDA meeting with industry related to ER/LA Opioid REMS. Based on feedback from the Advisory Committee meeting in May, the FDA intends 1) expand the REMS focus to include immediate release opioids and, 2) expand the blueprint to include other health professions that are part of the care team, and 3) educate all Opioid prescribers. Doris was unsure of the timeline.

Cynthia asked how soon non-prescriber team members would be included. Doris replied the intent was to have all happen at once. Mark asked Doris about the number of IR members invited. Doris mentioned approximately fifty companies were invited to the January meeting. Ilana wanted to confirm stakeholders will have opportunity to comment on blueprint revisions. Doris confirmed they would be considered part of the public comment. Valerie added the FDA still considers work of this working group important and continues to be interested in demographics on learners.

### 3 Review [feedback on questions raised at last meeting](#) (also see [instiutional prescriber in context](#) and [Additional fields form FDA](#))

Linda noted that since we are using a single definition and term for ER/LA opioid prescribers we should modify the definition to remove the reference to DEA registration. She also recommended removing the word registered from the terms schedule 2 or 3 registered clinician and schedule 2 or 3 registered clinicians successfully completing. Valerie modified all three definitions to apply to both those registered individually and those using institutional DEA registration.

Linda noted that the terms would capture answers to 2 different questions: can you prescribe and have you prescribed. Julie noted that there were discrepancies in the number of clinicians self-reporting prescribing behaviors. They tend to underreport by about 15 to 20%. She recommended looking at the number of completers authorized to prescribe.

Valerie offered to send to working group asking for comments in the next two weeks. The group noted that these changes would warrant changes to the questions that they ask participants. Both Ilana and Cynthia indicated that they ask if the clinician is registered to prescribe schedule 2 or 3 controlled substances, and within the last two months have you prescribed ER/LA Opioids. Valerie suggested capturing non-prescribers that have the ability to prescribe. Francis asked if non-prescribers are reported to the FDA, and Doris confirmed they were not.

Valerie noted that she would deprecate the old definition of ER LA opioid prescriber. The definition should be kept for historical purposes, but after a certain date we won't want people to use it going forward. She noted that the group should set a recommended date for implementation to provide consistency on rollout.

Cynthia commented REMS assessments are important regarding the disparity between learner-reported data verses survey participant data. The group discussed the definition of specialties provided in Healthcare LOM. Valerie noted there are no standard definitions of specialties in Healthcare LOM. Francis asked if anyone shared their list of specialties with the group. Boston confirmed they had shared via email which Valerie circulated. The group will move forward with the current list. The FDA indicated they would like to collect specialty data to obtain better feedback.

### 4 Identify next steps

Valerie and Francis conferred following the meeting and agreed to move forward with revised implementation guidelines.

## Decisions

- The following definitions were modified: ER/LA\_opioid\_prescriber\_2017, schedule\_2\_or\_3\_clinician, schedule\_2\_or\_3\_clinicians\_successfully\_completing.
- We will move forward with incorporating specialty data into the implementation guidelines.

## Action Items

- Providers will develop modified questions to reflect the new definitions.
- The group will discuss deprecating terms on a specific date once they are no longer in use.