2015-10-27

Meeting Information

Date:	October 27, 2015
Time:	11 AM PDT/12 PM MDT/1 PM CDT/2 PM EDT

Attending: Francis Kwakwa, Chair; Doris Auth, Caitlyn Briggs, Ilana Hardesty, Cynthia Kear, Helen Kim, Nathan Kopper, Joanna Krause, Jack Kues, Christina Mayne, Lauren Miller, Tom Prevoznik, Valerie Smothers, Lorraine Spencer, John Sweeney, John West, and Julie White.

Agenda Items

Valerie provided a brief overview. The Medical Education Metrics standard is used by the ACCME PARS system to collect data for CME providers. A few years ago Dr. Murray Koppelow suggested expanding the MEMS standard to collect data on CE related to extended release/long acting risk evaluation and mitigation strategy, ER/LA opioid REMS. This working group was convened to develop Medical Education Metrics (MEMS) 2.0 to address those needs. We are requesting feedback on what other data is needed as well as changes to the draft standard or guidelines.

1 Overview of requested changes to guidelines

Caitlyn explained that after the RPC submitted its 36 month report, the FDA requested data they are currently not collecting came. The FDA requested profession and specialty-type data for those participants who do not meet the definition of prescriber as well data on those prescribers who are practicing under an institutional DEA registration. The RPC felt that changes to the prescriber definition could help them capture that data.

2 Discussion of institutional DEA registration and prescriber definition

Tom explained physicians in training don't have a DEA registration of their own and use an institutional number. The institution applies a suffix to the DEA number to track who wrote the prescription or order. Valerie clarified every hospital that has residents that prescribe Opioids would have institutional registration. Tom mentioned there are six conditions where they can extend that authority to allow treating hospital or clinic patients at those locations, but many decide not to extend authority. Doris explained that the FDA wants to count as many prescribers as it can. Cynthia added that PA's and NP's don't have DEA registration but often use the DEA number of a physician in their practice. Tom commented there is no legal authority to extend to anyone else. Jennifer commented there are two ways to approach the problem: modify the existing definition of prescriber or come up with a separate term for those prescribing under institutional registration. Doris and Valerie will come back with a proposed resolution.

Jennifer asked if the FDA would want detailed data (brakdowns) of institutional prescribers or just the total number. Doris was not sure. She will discuss with her team to see what their level of interest is. Francis asked what other institutions would look like. Tom noted big institutions fall under hospital or clinics. Francis asked if they were not interested in institution type. Doris will ask her team but she suspected not. Valerie added it if we wanted type we would have to define it. Cynthia encouraged the group to capture PA's and NP using physicians DEA numbers. Francis didn't think that was likely to happen. Lauren clarified that and NP or PA may be able to prepare the prescription for signature, but only the registrant can sign the prescription.

Doris will present results to management in December. Valerie commented CE providers submit to ACCME and other accreditors in February and proposed implementing changes as soon as January. Nathan clarified the RPC data cutoff date is Feb 28 of each year. Full implementation will be in 2017. Valerie added the key is that CE providers would have to make changes to surveys by a particular date. We need to ensure there is enough time to give guidance and make changes. Julie mentioned Boston University would need time for the data collection process. In addition, the ACCME and other needs time to add fields to PARS. Other accreditors would need to make changes as well. She requested the group reach out to past participants that may have missed being counted. Jennifer commented their internal deadline is March 31, so they are ramping up the 2015 reporting period now. She will provide a better timeframe when they know more. Francis added implementation can go fairly quickly once definitions are out. Valerie hoped to have initial feedback within a week.

3 Discussion of profession and specialty data collection

Doris with discuss with her colleagues then she and Valerie will working on draft definitions and revising guidelines to indicate professional specialty.

4 Open discussion

Decisions

Action Items

Doris will present the following questions to FDA management in December:

- Do they want to capture institutional prescribers and those with the ability to prescribe under institutional registration? Should institutional prescribers be captured separately from other kinds of prescribers?
- If they do want to capture the number of institutional prescribers, do they also want detailed data on institutional prescriber specialty, profession, or institution type?