

Letter on data collection

Sent May 4, 2018

Dear working group,

One the last call, we spent much time discussing when accreditors and providers should switch over from ER/LA Opioid REMS to the broader Opioid REMS. I just wanted to clarify a few things about the MedBiquitous standard and the new REMS.

Broadly speaking, these are two different REMS. The ER/LA Opioid REMS has a much narrower scope, with regards to the medications to which it applies and to the blueprint of the course. The new Opioid REMS applies to more medications and has a broader blueprint.

In addition, the demographic data requested differs from the ER/LA Opioid REMS to the new, broader Opioid REMS. There are new demographic requirements in the Opioid REMS: some things not collected for ER/LA REMS, some things that are similar to what was collected for ER/LA REMS but the possible answers are different, and the granularity of reporting is different (ie at the level of the learner rather than aggregate data).

The MedBiquitous metrics standard anticipated that new REMS would be released and provided a mechanism for indicating to which REMS the learning activity was compliant. We even provide a place for the unique identifier for the version of the REMS just in case multiple versions of the same REMS are released – you can distinguish which version the data applies to.

It is not necessary to have all providers and accreditors “switch” from ER/LA to the broader Opioid REMS on a single date. Accreditors may choose to collect data in parallel for ER/LA Opioid REMS and Opioid REMS. Providers may have older courses that are compliant to the ER/LA REMS and newer courses that are compliant to the broader Opioid REMS. Or providers may just develop courses compliant to the newer, broader Opioid REMS. In order to be considered compliant with the new, broader Opioid REMS, and activity must:

- a) Adhere to Blueprint requirements for the new REMS
- b) Have evaluation or registration questions matching the requirements expressed in the LearnerDataFinal document that we reviewed (attached).
- c) Have the ability to collect and convey de-identified learner level data.
- d) Have a post course knowledge assessment that learners must pass to be considered successfully completing.

There may be some instances where a course is transitioning from compliance with ER/LA Opioid REMS to compliance with the new, broader Opioid REMS. In that case, the provider can choose when that transition happens based on when they are able to meet requirements A-D above. They can begin collecting the data, and the accreditors can prepare to accept that data.

Does this mean that accreditors who did not receive REMS data from providers previously must now be able to receive data for both ER/LA REMS and the new, broader Opioid REMS? No, it does not. Accreditors can make their own decisions for which REMS they will collect data.

I hope this helps to clarify. If you have questions or concerns, as always, feel free to contact me. My intent is to clarify what our standards will support. As always, business decisions may be influenced by other factors.

Best,

Valerie