Medical Education Metrics Implementation Guidelines for REMS CE Data Exchange

Version History

Version No.	Date	Changed By	Changes Made
0.1	February 11, 2013		Initial draft
0.2	February 19, 2013	Valerie Smothers	Updated table of contents, Updated 3.4.3 & 3.4.4. to be prescribers successfully completing by profession and practice type.
0.3	February 26, 2013	Valerie Smothers	Clarified that there should be one response for practice type, and only presented to prescribers of certain professions; added the words post-course prior to assessment, added information about a provider supplied identifier.
0.4	March 12, 2013	Valerie Smothers	Deleted "active" before prescribers to be consistent in our use of terminology.
0.5	April 1, 2013	Valerie Smothers	Added instructions for including activityLocation, startDateTime, activityFormat, RPC generated activity ID, accreditor generated activity ID, commercial supporter (using the CommercialSupportAmount supportSource attribute). Removed JointlyAccredited and CommercialSupporter.
0.51	April 3, 2013	Valerie Smothers	Added example for activityLocation and activityFormat; corrected example for startDateTime.
0.52	April 4, 2013	Valerie Smothers	Clarification regarding the use of country code.

0.6	April 26, 2013	Valerie Smothers	Added instructions for conveying Number of participants successfully completing and Number of participants successfully completing registered to prescribe schedule 2 and 3 drugs. Added appendix for sample survey questions (from BU and CORE).
0.61	May 10, 2013	Valerie Smothers	Changed definitions referenced to schedule_2_or_3_registered_prescriber and schedule_2_or_3_registered_prescribers_successfull y_completing
0.62	May 24, 2013	Valerie Smothers	Update to a registration question in Appendix with examples of Schedule 2 and 3 opioid analgesics.
0.63	June 7, 2013	Valerie Smothers	Changed drugs to controlled substances.
0.64	June 18, 2013	Valerie Smothers	Added "or" where needed for describing registered prescribers. Updated language in appendix to be consistent with "controlled substances" terminology.
0.65	July 17, 2013	Valerie Smothers	Added accurate URLs from the FDA website.
0.66	October 2, 2013	Valerie Smothers	Revised 3.4 to indicate that collecting the number of prescriber participants is not mandated by the REMS. Changed references to schedule 2 or 3 registered prescribers to schedule 2 or 3 registered clinicians.
.067	March 13, 2014	Valerie Smothers	Revised Section 3, General Guidelines, to reflect the agreed upon dates for data submission.

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Table of Contents

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2   Overview

As the Institute of Medicine and others call for reforms to Continuing Medical Education and other types of Continuing Education (CE) for the health professions, there has been an increasing focus on measuring the quality of CE activities. Educators, Accreditors, CE supporters, and government agencies often collect aggregate data on the reach and efficacy of CE activities in order to gauge improvement.

Medical Education Metrics (MEMS) ver. 2.0 was designed to support the compilation of data in support of Food and Drug Administration (FDA) Risk Evaluation and Mitigation Strategies, or REMS. The extended-release and long-acting (ER/LA) opioid analgesics REMS program (ER/LA REMS) currently mandates manufacturers to make "REMS-compliant training" available to Health Care Providers (HCPs) who prescribe ER/LA opioid analgesics, and FDA, the Accreditors and RPC have agreed that accredited continuing education can fulfill this requirement of the REMS. Since companies regulated by the FDA are required to collect educational outcomes data, demographics, and other metrics related to the reach and impact of the activity, and since it is anticipated that there will be multiple bodies reporting data, a standardized way of collecting/reporting this information is needed .

The MEMS standard provides a data structure that allows for the exchange of REMS CE-related data. This Implementation Guideline provides general guidance for those organizations implementing MEMS n support of ER/LA REMS CE data collection or dissemination.

The MEMS standard allows for the exchange of broader CE related data, and accrediting bodies may require more detailed information for accreditation purposes. Such use of MEMS is entirely valid and conformant with the standard, but it is not the topic of this implementation guideline.

3   General Guidelines

The following types of data are required for ER/LA Opioid REMS CE data.

- Reporting information
- Activity information
- Regulatory information
- Participation Metrics

Accredited providers should send data current through Feb 28 to accreditors by March 31.

Accreditors send data to Polaris/RPC by May 9. Accreditors may choose to submit data to the RPC earlier at their sole discretion.

More information on each type of data follows.

3.1   Reporting Information

When communicating data on a CE activity, it's important to note the period for which you are reporting data. Use the following sub-elements of the ReportDescription element to identify the first and last day of the period for which you are reporting data.

- ReportingStartDate
- ReportingEndDate

Example:

```
<ReportDescription>
    <ReportingStartDate>2013-01-01</ReportingStartDate>
    <ReportingEndDate>2013-12-31</ReportingEndDate>
</ReportDescription>
```

3.2   Activity Information

MEMS allows for the exchange of detailed information about the activity that is the subject of the metrics report. REMS CE requires the following data points.

3.2.1   Accrediting Body

The organization that sets the quality standards for continuing education and is the source of the accreditation process for this activity. The following values are recommended for REMS CE: AAFP, ACCME, ACPE, ADA, ANCC, AOA, APA, ARBO.

The accrediting body is conveyed using the accreditingBody element of Healthcare LOM [Healthcare LOM]. See the example at the end of this section for more details.

3.2.2   Activity Identifier

An identifier for the activity provided by the CE provider must be included in the data set. The Activity Identifier provided by the CE provider will help to eliminate double-counting of data for activities offered for multiple types of credit.

In addition, an identifier for the activity provided by the RPC or by the accreditor may be included in the data set.

The Activity Identifier is conveyed using the identifier element of Healthcare LOM [Healthcare LOM]. Repeat the identifier element to include multiple identifiers for an activity. For example, some instances may include the identifier generated by the provider as well as the identifier generated by the RPC.

See the example at the end of this section for more details.

3.2.3   Title

The title of the CE activity. The title is conveyed using the title element of Healthcare LOM [Healthcare LOM].

See the example at the end of this section for more details.

3.2.4   Accredited provider

The entity serving as the accredited provider for this activity. Accredited provider is conveyed using the accreditedProvider element of Healthcare LOM [Healthcare LOM].

See the example at the end of this section for more details.

3.2.5   Activity Location

The geographical location in which an in person activity takes place. Activity location is conveyed using the activityLocation element is Healthcare LOM [Healthcare LOM]. If an activity is not face to face, the activity location element should not be used.

MedBiquitous recommends using the following subelements of activityLocation:

- City
- StateOrProvince
- Country

Note that Country has two subelements: CountryName and CountryCode. For REMS CE, use CountryCode element with the ISO 3166 three-letter alpha code (i.e. USA). See ANSI /MEDBIQ PP.10.1-2008 Address Specifications and Description Document [Address] and the example at the end of this section for more details.

3.2.6   Activity Date

Use the startDateTime element of Healthcare LOM to indicate the date and time that a live activity begins [Healthcare LOM]. startDateTime uses the dateTime format. For example, 2013-01-31T09:00:00.

3.2.7   Activity type

The type of learning activity described. Activity Type is conveyed using the activityFormat element of Healthcare LOM [Healthcare LOM].

See the example at the end of this section for more details.

3.2.8   Commercial Supporter

The commercial organization providing support for this activity. In some cases, the REMS Program Companies provide commercial support for REMS CE.

MEMS uses the commercialSupportAmount element to convey commercial supporter data. In this case the supportSource attribute would have a value of REMS Program Companies. If no commercial support amount data is being exchanged, use XML Schema instance nil attribute with a value of true.

Example:

```
<ActivityDescription>
   <lom:lom>
      <lom:general>
         <lom:identifier>
            <lom:catalog>Provider Activity ID</catalog>
            <lom:entry>123456</lom:entry>
         </lom:identifier>
         <lom:identifier>
            <lom:catalog>RPC generated ID</catalog>
            <lom:entry>234567</lom:entry>
         </lom:identifier>
         <lom:title>
            <lom:string>
              Addressing the Risks of Pain Management
            </lom:string>
         </lom:title>
      </lom:general>
      <hx:healthcareMetadata>
         <hx:healthcareEducation>                      <hx:credits>
            <hx:accreditingBody>ACCME</hx:accreditingBody>
            <hx:accreditedProvider>
              NoSuch Society
            </hx:accreditedProvider>
         </hx:credits>
         <hx:activityLocation>
            <a:City>Baltimore</a:City>
            <a:StateOrProvince>MD</a:StateOrProvince>
            <a:Country>
               <a:CountryCode>US</a:CountryCode>
            </a:Country>
```

```
        </hx:activityLocation>
        <hx:startDateTime>2013-01-31T09:00:00</hx:startDateTime>
        <hx:activityFormat>
            <lom:string>Course</lom:string>
            </hx:activityFormat>
    </hx:healthcareEducation>
        </hx:healthcareMetadata>
    </lom:lom>
        <CommercialSupportAmount supportSource="REMS Program Companies"
xsi:nil="true"/></ActivityDescription>
```

3.3 Regulatory Information

When reporting on REMS CE activities, it is important to indicate whether or not the activity is compliant to all of the requirements set out for CE activities by the REMS ER/LA Opioid REMS regulation. If an activity meets all of the requirements for CE activities set out in the ER/LA opioid REMS regulation, see the section Compliant Activities.

If the activity meets some but not all requirements set out for CE activities by the ER/LA Opioid REMS regulation (for example, it addresses some but not all elements of the REMS blueprint), see the section Related Activities.

3.3.1 Compliant Activities

Use the CompliantToRegulation element to indicate that the activity described is compliant to requirements outlined in the REMS regulation. The value of CompliantToRegulation is the URI of the regulation. For ER/LA REMS, use the URI for the specific version of the REMS you are supporting. For example: http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/OpioidREMJuly2012.pdf

CompliantToRegulation has the following attribute:

label

A label for the regulation. For example, ER/LA Opioid REMS.

An example of regulatory information for an activity compliant with the ER/LA Opioid REMS requirements follows:

```
<RegulatoryInformation>
   <CompliantToRegulation label="ER/LA Opioid REMS">
http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/OpioidREMJuly2012
.pdf
   </CompliantToRegulation>
</RegulatoryInformation>
```

3.3.2 Related Activities

Indicate the activity is related to the REMS

Use the RelatedToRegulation element to indicate that the activity is related to the REMS regulation but does not meet all requirements set out for CE activities by the REMS regulation (for example, it addresses some but not all elements of the REMS blueprint). The value of RelatedToRegulation element is the URI of the regulation. For ER/LA REMS, use the URI for the specific version of the REMS you are supporting. For example:

http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/OpioidREMJuly2012.pdf

RelatedToRegulation has the following attribute:

label

A label for the regulation. For example, ER/LA Opioid REMS.

Indicate which sections of the blueprint are addressed by instruction and assessment

Use the RegulatoryClassification element and its subelements to indicate which REMS blueprint components (sections or elements) are addressed and how they are addressed. You should indicate which section(s) of the blue print are addressed by the instruction and/or assessment if the activity being reported is related to the regulation but not compliant to the regulation.

Use the subelements of RegulatoryClassification to specify each section addressed in the instruction and each section addressed in the assessment.

RegulatoryClassification has the following subelements:

- **ClassificationRelation** – either Assessment Addresses and Instruction Addresses
- **Regulation** – the URI of the regulation. For example,
  http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/OpioidREMJuly2012.pdf.
  Regulation has a label attribute which should have the value ER/LA Opioid REMS.
- **ComponentID** – The identifier for the blueprint section. For example, II.
- **ComponentTitle** – The title for the blueprint section. For example, Initiating Therapy, Modifying Dosing, and Discontinuing Use of ER/LA Opioid Analgesics.

```
<RegulatoryInformation>
    <RelatedToRegulation label="ER/LA Opioid REMS">
http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/OpioidREMJuly2012
.pdf
    </RelatedToRegulation>
    <RegulatoryClassification>
        <ClassificationRelation>
          Instruction Addresses
        </ClassificationRelation>
        <Regulation label="ER/LA Opioid REMS">
http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/OpioidREMJuly2012
.pdf
        </Regulation>
        <ComponentID>II</ComponentID>
        <ComponentTitle>
```

```
        Initiating Therapy, Modifying Dosing, and Discontinuing Use of
        ER/LA Opioid Analgesics
      </ComponentTitle>
    </RegulatoryClassification>
    <RegulatoryClassification>
      <ClassificationRelation>
        Assessment Addresses
      </ClassificationRelation>
      <Regulation label="ER/LA Opioid REMS">
  http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/OpioidREMJuly2012
  .pdf
      </Regulation>
      <ComponentID>II</ComponentID>
      <ComponentTitle>
        Initiating Therapy, Modifying Dosing, and Discontinuing Use of
        ER/LA Opioid Analgesics
      </ComponentTitle>
    </RegulatoryClassification>

  </RegulatoryInformation>
```

3.4 Participation Metrics

Providers must report a few key participation metrics for REMS CE. The FDA mandates the collection of information on how many active ER/LA Opioid prescribers successfully completed the activity and a breakdown prescribers successfully completing by profession. The MEMS 2.0 specification also allows for reporting of:

- Number of prescribers participating.
- A breakdown of prescribers successfully completing according to practice type.
- Number of participants successfully completing.
- Number of participants successfully completing registered to prescribe schedule 2 and/or 3 controlled substances.

The MedBiquitous Metrics Working group developed a vocabulary of practice types that are relevant to the ER/LA Opioid REMS and would provide the FDA with data on the audience reached by REMS CE. Primary care providers are a targeted audience for REMS CE. It's important for the FDA to know how many primary care providers are engaged in REMS CE, as well as how many pain specialists and non-pain specialists are engaged. While prescribers by practice type is optional data for providers to convey, conveying this data gives the FDA and the public a better view of the prescriber community engaged in REMS CE.

To avoid confusion, use the following guidelines for developing survey questions related to practice type data:

- Allow or instruct participants to choose the practice type that best describes their practice (one response only).

- Present the question on practice type only to those learners who are prescribers and are from one of the following professions:
  - Physician
  - Advanced practice nurse
  - Dentist
  - Physician assistant

Appendix 1 provides sample survey questions.

For REMS CE, use the definitions posted on the MedBiquitous website at:
http://www.medbiq.org/mems/definitions

Participants' prescriber status, profession, and practice type may be self reported. DEA registration status does not need to be verified. MedBiquitous recommends collecting data on learners' prescriber status at the beginning of a CE activity or during the registration process.

3.4.1   Prescribers

Use the ParticipantsByCategory element and its sub-elements to convey the number of prescribers participating. For a definition of prescribers, see:
http://www.medbiq.org/mems/definitions#ER/LA_opioid_prescriber
ParticipantsByCategory has the following sub-elements:

- **CategoryName** – Use ER/LA Opioid prescriber.
- **CategoryDefinition** – Use the URL:
  http://www.medbiq.org/mems/definitions#ER/LA_opioid_prescriber
- **Number** – the total number of participants meeting the definition of prescribers at defined at the URL above . For example, 190.

Example:

```
<ParticipantsByCategory>
    <CategoryName>ER/LA Opioid Prescriber</CategoryName>
    <CategoryDefinition>http://medbiq.org/mems/definitions#ER/LA_opioid_pre
scriber</CategoryDefinition>
    <Number>190</Number>
</ParticipantsByCategory>
```

3.4.2   Participants successfully completing

Use the ParticipantsByCategory element and its sub-elements to convey the number of participants successfully completing. ParticipantsByCategory has the following sub-elements:

- **CategoryName** – Use successfully completing.
- **CategoryDefinition** – Use the URL:
  http://www.medbiq.org/mems/definitions#successfully_completing
- **Number** – the total number of participants successfully completing. For example, 124.

Example:

```
<ParticipantsByCategory>
    <CategoryName>successfully completing</CategoryName>
    <CategoryDefinition>
    http://www.medbiq.org/mems/definitions#successfully_completing
    </CategoryDefinition>
    <Number>124</Number>
</ParticipantsByCategory>
```

3.4.3   Prescribers successfully completing

Use the ParticipantsByCategory element and its sub-elements to convey the number of prescribers successfully completing. ParticipantsByCategory has the following sub-elements:

- **CategoryName** – Use prescribers successfully completing.
- **CategoryDefinition** – Use the URL:
  http://www.medbiq.org/mems/definitions#prescribers_successfully_completing
- **Number** – the total number of prescribers successfully completing. For example, 89.

Example:

```
<ParticipantsByCategory>
    <CategoryName>prescribers successfully completing</CategoryName>
    <CategoryDefinition>
    http://www.medbiq.org/mems/definitions#prescribers_successfully_complet
    ing
    </CategoryDefinition>
    <Number>89</Number>
</ParticipantsByCategory>
```

3.4.4   Schedule 2 or 3 registered clinicians successfully completing

Use the ParticipantsByCategory element and its sub-elements to convey the number of Schedule 2 and/or 3 registered clinicians successfully completing. ParticipantsByCategory has the following sub-elements:

- **CategoryName** – Use schedule 2 or 3 registered clinicians successfully completing.
- **CategoryDefinition** – Use the URL:
  http://www.medbiq.org/mems/definitions#schedule_2_or_3_registered_clinicians_successfully_completing
- **Number** – the total number of Schedule 2 and/or 3 registered clinicians successfully completing. For example, 89.

Example:

```
<ParticipantsByCategory>
    <CategoryName>schedule 2 or 3 registered clinicians successfully
completing</CategoryName>
    <CategoryDefinition>
```

```
    http://www.medbiq.org/mems/definitions#schedule_2_or_3_registered_
    clinicians_successfully_completing</CategoryDefinition>
    <Number>89</Number>
</ParticipantsByCategory>
```

3.4.5   Prescribers successfully completing by profession

Use the MultipleCategories element and its sub-elements to convey the breakdown on prescribers successfully completing by profession. You must use a new MultipleCategories element for each profession represented. So if physicians, advanced practice nurses, and pharmacists participated in the activity, there should be three instances of the MultipleCategories element.

Use the following subelements of MultipleCategories to convey prescribers successfully completing by profession.

- **TotalNumber** - the total number of prescribers of this profession that successfully completed the activity.
- **Profession** – The profession for which you want to convey data. A list of prescriber professions for use in conveying ER/LA Opioid REMS data is available at: http://medbiq.org/mems/vocabularies
- **Category** – contains the subelements CategoryName and CategoryDefinition. To convey the category of prescribers successfully completing, CategoryName should have a value of prescribers successfully completing, and CategoryDefinition should have a value of: http://medbiq.org/mems/definitions#prescribers_successfully_completing

For example:

```
<MultipleCategories>
    <TotalNumber>134</TotalNumber>
    <Profession>Physician</Profession>
    <Category>
       <CategoryName>prescribers successfully completing</CategoryName>
       <CategoryDefinition>

http://www.medbiq.org/mems/definitions#prescribers_successfully_completing
       </CategoryDefinition>
    </Category>
</MultipleCategories>
<MultipleCategories>
    <TotalNumber>20</TotalNumber>
    <Profession>Advanced Practice Nurse</Profession>
    <Category>
       <CategoryName>prescribers successfully completing</CategoryName>
       <CategoryDefinition>

http://www.medbiq.org/mems/definitions#prescribers_successfully_completing
       </CategoryDefinition>
    </Category>
```

```
</MultipleCategories>
```

3.4.6   Prescribers successfully completing by practice type

Use the MultipleCategories element and its sub-elements to convey the breakdown on prescribers successfully completing by practice type. Breakdown by practice type is optional data for CE providers to convey but helps in assessing the reach of REMS CE. You must use a new MultipleCategories element for each practice type represented. So if primary care, pain specialist, and non-pain specialist providers participated in the activity, there should be three instances of the MultipleCategories element.

```
<MultipleCategories>
    <TotalNumber>123</TotalNumber>
    <PracticeType>Primary care</PracticeType>
    <Category>
        <CategoryName>prescribers successfully completing</CategoryName>
        <CategoryDefinition>

http://www.medbiq.org/mems/definitions#prescribers_successfully_completing
        </CategoryDefinition>
    </Category>
</MultipleCategories>
<MultipleCategories>
    <TotalNumber>23</TotalNumber>
    <PracticeType>Pain specialist</PracticeType>
    <Category>
        <CategoryName>prescribers successfully completing</CategoryName>
        <CategoryDefinition>

http://www.medbiq.org/mems/definitions#prescribers_successfully_completing
        </CategoryDefinition>
    </Category>
</MultipleCategories>
<MultipleCategories>
    <TotalNumber>18</TotalNumber>
    <PracticeType>Non-pain specialist</PracticeType>
    <Category>
        <CategoryName>prescribers successfully completing</CategoryName>
        <CategoryDefinition>

http://www.medbiq.org/mems/definitions#prescribers_successfully_completing
        </CategoryDefinition>
    </Category>
</MultipleCategories>
```

3.5   What constitutes an activity?

Providers must follow their accreditation body's guidelines regarding what constitutes an activity. For ACCME definitions of different activity types, see: http://www.accme.org/ask-accme/what-kind-cme-activity-types-can-be-reported-pars

3.6   Different formats of data exchange (paper, CSV, XML)

Different format may be used to send data to accreditors. Please check with your accreditor to see whether paper, Comma Separated Value (CSV – typically used for exchanging spreadsheets), or XML is acceptable for data exchange. There may be Excel templates or other templates available to facilitate the process of formatting your data.

4   References

Address

ANSI /MEDBIQ PP.10.1-2008 Address Specifications and Description Document. MedBiquitous Website. http://www.medbiq.org/working_groups/professional_profile/AddressSpecification.pdf. Published June 27, 2008.

Healthcare LOM

ANSI/MEDBIQ LO.10.1-2008, Healthcare Learning Object Metadata (Healthcare LOM). MedBiquitous Website. http://www.medbiq.org/std_specs/standards/index.html#HCLOM. Accessed June 1, 2011.

5 Appendix: Sample Survey Questions

The following sample survey questions have been included as examples of questions that may be used to collect REMS-specific demographic data.

The examples below have been provided by Boston University Continuing Medical Education.

5.1 Registration Questions

The following questions represent the subset of questions used by Boston University to collect data specific to the evaluation of REMS CE as described in this guideline. Please note that Boston University uses a more detailed list of professions for internal needs assessment purposes.

Profession: ((drop down list as follows))
Physician
Advanced practice nurse
Pharmacist
Dentist-

Dental Public Health

Dentist-Endodontics

Dentist-General Dentistry

Dentist-Oral and Maxillofacial Pathology

Dentist-Oral and Maxillofacial Radiology

Dentist-Oral and Maxillofacial Surgery

Dentist-Orthodontics and Dentofacial Orthopedics

Dentist-Pediatric Dentistry

Dentist-Periodontics

Dentist-Prosthodontics

Optometrist
Physician Assistant
Podiatrist
Psychologist
Other Mental health professionals
Nurse
          Other:
          ((If other)) Specify _____

We request the following prescribing data in order to ensure we are providing appropriate education for our audience. Thank you for completing the following information.

*Are you currently registered with the DEA to prescribe schedule II and/or schedule III controlled substances?

((Red text = pop up menu))

     ☐   Yes

     ☐   No

     ☐   Not sure

((POP Up menu text)):

_____

Schedule II and Schedule III Controlled Substances

Some examples of Schedule II and Schedule III controlled substances are listed below. For more information about specific medications, go to http://dailymed.nlm.nih.gov/dailymed/about.cfm and search on the medication name.

Schedule II and Schedule III Controlled Substances

Codeine
Buprenorphine
Dihydrocodeinone (hydrocodone)
Fentanyl
Hydromorphone
Meperidine
Methadone
Morphine
Oxycodone
Oxymorphone
Tapentadol

* Within the last 12 months, have you prescribed extended release long-acting (ER-LA) opioids? **((red text hyperlink= http://www.er-la-opioidrems.com/IwgUI/rems/products.action))**

     ☐   Yes

     ☐   No