RPC Website Screenshot Document

August 2018
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1. Home Page
Opioid Analgesic REMS for Accredited Continuing Education Providers

The Opioid Analgesic Risk Evaluation Mitigation Strategies (REMS) was designed to ensure that the benefits of opioid analgesics used in the outpatient setting outweigh the risks (in patients whose clinicians have determined opioid analgesics to be an appropriate treatment option). The FDA has required manufacturers of opioid analgesics, known as the REMS Program Companies (RPC), to make education available for providers of these medications. RPC-supported REMS education will be provided through accredited continuing education (CE) activities supported by independent educational grants from these opioid analgesic companies. To assist in this effort, the FDA has developed an Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain ("FDA Blueprint") that is posted on the FDA website.

To date, the RPC has completed 4 Grant cycles; see the table below for a listing of grant awardees from the 2012, 2013, 2014, and 2015 Grant cycles. As of October 2015, a detailed list of over 50 individual RPC-supported REMS-compliant accredited CE activities is available on the CE Search Page. Please note that accredited CE Providers are still finalizing dates/locations for some of the activities. Check back often as this listing will be updated on a regular basis.

### Grants Supported from 2017 RFA

<table>
<thead>
<tr>
<th>Primary Provider</th>
<th>Partners</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trustees of Boston University</td>
<td>Haymarket Medical Education, Council of Medical Specialty Societies, and 6 governmental and professional organizations</td>
<td>Safe and Competent Opioid Prescribing Education for Chronic Pain (SCOPE of Pain): Incorporating ER/LA Opioid Analgesics REMS into Practice</td>
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<tr>
<td>Johns Hopkins University</td>
<td>DKBmed</td>
<td>Get SMART ‘Mobile’ - Safe Means of Administering the Right Therapy (Get SMART Mobile)</td>
</tr>
<tr>
<td>Postgraduate Institute of Medicine</td>
<td>DKBmed</td>
<td>Safe Means of Administering the Right Therapy - Extended-Release and Long-Acting Opioids (Get SMART ER/LA Opioids)</td>
</tr>
<tr>
<td>Pri-Med Institute</td>
<td>American College of Physicians</td>
<td>SAFE Opioid Prescribing, Strategies, Assessment, Fundamentals, and Education</td>
</tr>
<tr>
<td>CO’RE</td>
<td>11 National &amp; State Medical Societies, Medscape, and 50+ cooperating organizations</td>
<td>Opioid Prescribing Safe Practice, Changing Lives</td>
</tr>
<tr>
<td>Global Education Group</td>
<td>Rockpointe Corporation, PAINWeek, Primary Care Network, and FreeCME</td>
<td>Extension Grant: Extended-Release and Long-Acting Opioid Analgesics: Risk Evaluation and Mitigation Strategy (REMS)</td>
</tr>
</tbody>
</table>

### Grants Supported from 2016 RFA

- Request for Application (RFA) 080317 Extension (2017 Grant Review Cycle)
- Listing of Opioid Analgesic REMS Program Companies (RPC) NEW
- Listing of Accredited CE REMS-Compliant Activities Supported by RPC UPDATED
- Frequently Asked Questions regarding Continuing Education UPDATED
- CE Grant Management System
- Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain ("FDA Blueprint") UPDATED
- Press Release about MedBiquitous Standards Development
<table>
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<th>Rockpointe Corporation, PAINWeek, Primary Care Network, and FreeCME</th>
<th>Extension Grant: Extended-Release and Long-Acting Opioid Analgesics: Risk Evaluation and Mitigation Strategy (REMS)</th>
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<td>Grants Supported from 2015 RFA</td>
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<td>Grants Supported from 2014 RFA</td>
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<td>Grants Supported from 2013 RFA</td>
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<tr>
<td>Grants Supported from 2012 RFA</td>
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For further information on the Opioid Analgesic REMS, please refer to the [FDA website](https://www.fda.gov).

For further inquiries relating to educational grants for the Opioid Analgesic REMS, please refer to the [Continuing Education Frequently Asked Questions (FAQs)](https://www.continuingeducation.com/FAQs).
### Products Search

Use the filters below to search the products.

<table>
<thead>
<tr>
<th>Drug Name / Trade Name</th>
<th>Generic Name</th>
<th>Company</th>
<th>Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lozitac®</td>
<td>(morphine sulfate) extended-release tablets, for oral use CII</td>
<td>Egalet Corporation</td>
<td>1-800-518-1084</td>
</tr>
<tr>
<td>Beibucal®</td>
<td>Buprenorphine buccal film</td>
<td>BioDelivery Sciences International, Inc</td>
<td>1-877-579-4575</td>
</tr>
<tr>
<td>Butrans®</td>
<td>Buprenorphine transdermal system</td>
<td>Purdue Pharma L.P.</td>
<td>1-866-726-7535</td>
</tr>
<tr>
<td>Dolophine®</td>
<td>Methadone hydrochloride tablets</td>
<td>West-Ward Pharmaceuticals Corp.</td>
<td>1-800-962-5364</td>
</tr>
<tr>
<td>Duragesic®</td>
<td>Fentanyl transdermal system</td>
<td>Janssen Pharmaceuticals, Inc.</td>
<td>1-800-526-7736</td>
</tr>
<tr>
<td>Embeda®</td>
<td>Morphine succinate and naloxone extended-release capsules</td>
<td>Pfizer Inc.</td>
<td>1-800-433-1985</td>
</tr>
<tr>
<td>EXALGO®</td>
<td>Hydromorphone hydrochloride extended-release tablets</td>
<td>Mallinckrodt LLC</td>
<td>1-800-775-7998</td>
</tr>
<tr>
<td>Hysingla™ ER</td>
<td>Hydrocodone bitartrate extended-release tablets</td>
<td>Purdue Pharma L.P.</td>
<td>1-866-726-7335</td>
</tr>
<tr>
<td>Kadian®</td>
<td>Morphine sulfate extended-release capsules</td>
<td>Allergan Sales, LLC</td>
<td>1-562-261-7000</td>
</tr>
<tr>
<td>Methadose™</td>
<td>Methadone hydrochloride tablets</td>
<td>Mallinckrodt LLC</td>
<td>1-800-775-7893</td>
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</tbody>
</table>

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Last Updated: February 1, 2018
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REMS-compliant Accredited CE for Opioid Analgesics

Healthcare providers who prescribe opioid analgesics have a responsibility to help ensure the safe and effective use of opioid analgesics. The FDA REMS-compliant accredited continuing education (CE) programs will focus on the safe prescribing of opioid analgesics.

The FDA REMS-compliant accredited CE will: (a) be delivered by accredited CE providers; (b) cover all elements of the updated Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain (“FDA Blueprint”); (c) include a knowledge assessment; and (d) be subject to independent audit of content and compliance with applicable accrediting standards.

The FDA has developed core messages to be communicated to providers in the Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain (“FDA Blueprint”), which will be used by accredited CE Providers to develop the REMS-compliant accredited CE programs.

These core messages include:

- The fundamental concepts of pain management, including definitions and mechanisms of pain.
- Be familiar with how to assess patients in pain, identify risk factors for misuse, abuse, and addiction.
- Be familiar with how to integrate opioid analgesics into a pain treatment plan individualized to the needs of the patient.
- Be knowledgeable about how the range of therapeutic options for managing pain, including nonpharmacologic approaches and pharmacologic (non-opioid and opioid analgesics) therapies and when to refer to a pain specialist is appropriate.
- Know how to safely and effectively manage patients on opioid analgesics in the acute and chronic pain settings, including initiating therapy, titrating, and discontinuing use of opioid analgesics.
- Know how to counsel patients and caregivers about the safe use of opioid analgesics, including proper storage and disposal.
- Be familiar with the fundamental elements of an addiction medicine and how to identify and manage patients with opioid use disorder.
- Be knowledgeable about how to counsel patients and caregivers about the use of naloxone for opioid overdose.

Click here for a listing of available FDA REMS-compliant accredited CE activities supported by independent educational grants from the opioid analgesic sponsors and offered by accredited CE Providers.
Patient Counseling Guide

What is the Patient Counseling Guide?

The Patient Counseling Guide on Opioid Analgesics is a tool unique to this REMS designed to facilitate important discussions with your patients for whom you select an opioid analgesic. The Patient Counseling Guide should be provided to and reviewed with the patient and/or their caregiver at the time of prescribing. It contains important safety information about the drug products subject to this REMS program and includes space for you to write additional information to help your patients use their opioid analgesic safely.

How can I obtain copies of the Patient Counseling Guide?

Printed copies of the Patient Counseling Guide (English) can be ordered either through an on-line order or via fax. Detailed instructions for both methods of ordering printed copies of the Patient Counseling Guide (English) can be found in the Patient Counseling Guide Order Form, and an electronic version of the Patient Counseling Guide (English and Spanish) is also available for download.
Opioid Analgesic REMS Letters

Click on the letter title below to open a PDF version of that letter:

- Dear Healthcare Provider (HCP) Letter #1
- Dear Professional Society and Licensing Board (PSLB) Letter #1
9. FAQ Pages

Note: The RPC Sponsors attest that the questions and answers on the FAQ screens will align with the FAQ document included in the submission.