Risk Evaluation and Mitigation Strategy (REMS) Document

Opioid Analgesic REMS Program

The Opioid Analgesic REMS Program includes all opioid analgesics used in the outpatient setting and not covered by other REMS programs.

I. Administrative Information

Initial Shared System REMS Approval: 07/2012
Most Recent REMS Update: 09/2018

II. REMS Goal

The Opioid Analgesic REMS is an educational effort and one of a number of national efforts that are designed to address the epidemic of prescription opioid abuse.

The goal of the Opioid Analgesic REMS is to educate prescribers and other healthcare providers (including pharmacists and nurses) on the treatment and monitoring of patients with pain. The education provided through the REMS program is based on the Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain (“FDA Blueprint”). Through better education, the healthcare team will have an improved understanding of how to manage pain and the role of opioid analgesics along with nonpharmacologic and non-opioid analgesics in pain management. The education will also provide information about the risks of opioids and use of other therapies which is intended to assist healthcare providers in reducing adverse outcomes of addiction, unintentional overdose, and death resulting from inappropriate prescribing, abuse, and misuse. The REMS will accomplish this goal by:

1. Ensuring that training based on the FDA Blueprint is effective in educating prescribers and other healthcare providers involved in the treatment and monitoring of patients in pain (including pharmacists and nurses) about recommended pain management practices and appropriate use of opioid analgesics.

2. Informing patients about their roles and responsibilities regarding their pain treatment plan, including the risks of opioid analgesics and how to use and store them safely, as outlined in the Medication Guides and Patient Counseling Guide for opioid analgesics.

III. REMS Requirements

Opioid Analgesic Applicants must make training available to healthcare providers who prescribe and healthcare providers involved in the treatment and monitoring of patients who receive opioid analgesics.

The training must include all the elements of the FDA Blueprint. The training must be made available to healthcare providers who prescribe or are involved in the treatment and monitoring (including pharmacists and nurses) of patients who receive opioid analgesics.

Training is compliant with the REMS if it: 1) for training provided by Continuing Education (CE) Providers, is offered by an accredited CE Provider and supported by unrestricted educational grants from the opioid analgesic applicants; 2) includes all elements of the FDA Blueprint; 3) includes a knowledge assessment of
all sections of the FDA Blueprint; and 4) is subject to independent audit to confirm that conditions of the REMS training have been met.

To inform healthcare providers about the REMS Program and the risks and safe use of opioid analgesics, Opioid Analgesic Applicants must disseminate REMS communication materials according to the table below:

<table>
<thead>
<tr>
<th>Target Audience</th>
<th>Communication Materials &amp; Dissemination Plans</th>
</tr>
</thead>
<tbody>
<tr>
<td>All DEA-registered prescribers, pharmacies, hospitals, and teaching institutions registered to prescribe or dispense Schedule II, III, and IV drugs</td>
<td>REMS Letter: Healthcare Provider Letter 1 or Professional Society/Licensing Board Letter 1 with attachment Patient Counseling Guide</td>
</tr>
<tr>
<td></td>
<td>1. Email within 60 calendar days of the approval (09/18/2018) of the REMS.</td>
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<tr>
<td></td>
<td>a. Send by mail within 30 calendar days of the date the first email was sent if a healthcare provider’s email address is not available or the email is undeliverable.</td>
</tr>
<tr>
<td></td>
<td>b. Send a second email within 30 calendar days of the date the first email was sent if the first email is marked as unopened.</td>
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<tr>
<td></td>
<td>c. Send by mail within 30 calendar days of the date the second email was sent if the second email is marked as unopened.</td>
</tr>
<tr>
<td></td>
<td>2. Disseminate through the following professional societies and request the letter or content be provided to their members:</td>
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<tr>
<td></td>
<td>a. The professional societies identified in Appendix A.</td>
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<tr>
<td></td>
<td>3. Disseminate through all dental, medical (allopathic and osteopathic), nursing, and pharmacy licensing boards and request the letter or content be provided to their licensed practitioners.</td>
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<td></td>
<td>4. Email within 30 calendar days of 03/31/2019.</td>
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<tr>
<td></td>
<td>a. Send by mail within 30 calendar days of the date the first email was sent if a healthcare provider’s email address is not available or the email is undeliverable.</td>
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<td><strong>Communication Materials &amp; Dissemination Plans</strong></td>
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</tr>
<tr>
<td>All newly DEA-registered prescribers, pharmacies, hospitals, and teaching institutions registered to prescribe or dispense Schedule II, III, and IV drugs since the last dissemination</td>
<td>REMS Letter: <a href="#">Healthcare Provider Letter 2</a> with attachment <a href="#">Patient Counseling Guide</a></td>
</tr>
</tbody>
</table>

1. **Email annually from the date of the approval (09/18/2018) of the REMS.**
   a. Send by mail within 30 calendar days of the date the first email was sent if a healthcare provider’s email address is not available or the email is undeliverable.
   b. Send a second email within 30 calendar days of the date the first email was sent if the first email is marked as unopened.
   c. Send by mail within 30 calendar days of the date the second email was sent if the second email is marked as unopened.

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**To support REMS Program operations, Opioid Analgesic Applicants must:**

1. Establish and maintain a REMS Program website, [www.opioidanalgesicrems.com](http://www.opioidanalgesicrems.com). The REMS Program website must include a current list of training funded by the Opioid Analgesic Applicants that is REMS-compliant and the option to print the PI, Medication Guide, and REMS materials. All product websites for consumers and healthcare providers must include prominent REMS-specific links to the REMS Program website. The REMS Program website must not link back to the promotional product websites.

2. Direct CE Providers to the [FDA Blueprint](http://www.fda.gov/OpioidAnalgesicREMSBlueprint).

3. Make the REMS Program website fully operational and all REMS materials available through the website and call center within 60 calendar days of REMS approval (09/18/2018).

4. Establish and maintain a REMS Program call center for healthcare providers at 1-800-503-0784.

5. Ensure healthcare providers who prescribe or are involved in the treatment and monitoring of patients who receive opioid analgesics are able to access training by 3/31/2019.

6. Notify accredited CE Providers of REMS-compliant training regarding changes to the [FDA Blueprint](http://www.fda.gov/OpioidAnalgesicREMSBlueprint) within 10 calendar days of such changes.

7. Use independent auditors (accreditation bodies of CE Providers are considered independent and eligible to conduct the audits) to audit the educational materials used by the accredited CE Providers of REMS-compliant training of a random sample of at least 10% of the training funded by the Opioid Analgesic Applicants to evaluate (1) whether the content of the training covers all the components of the [FDA Blueprint](http://www.fda.gov/OpioidAnalgesicREMSBlueprint), (2) whether the knowledge assessment measures knowledge of all sections of the [FDA Blueprint](http://www.fda.gov/OpioidAnalgesicREMSBlueprint), (3) whether the training was conducted in accordance with the standards for CE of the Accreditation Council for Continuing Medication Education or of another CE accrediting body appropriate to the prescribers, dental, pharmacy, nursing, or healthcare profession.

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**IV. REMS Assessment Timetable**

Opioid Analgesic NDA Applicants must submit REMS Assessments at 6 months, 12 months, and annually thereafter from the date of the approval of the REMS (09/18/2018). To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date.
for that assessment. Opioid Analgesic NDA Applicants must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the Opioid Analgesic REMS:

Training and Educational Materials

Healthcare Provider:

1. Healthcare Provider training available at www.opioidanalgesicrems.com

Patient:

3. Patient Counseling Guide

Communication Materials

4. Healthcare Provider Letter 1
5. Healthcare Provider Letter 2
6. Professional Society/Licensing Board Letter 1
7. Professional Society/Licensing Board Letter 2

Other Materials

8. Opioid Analgesic REMS Education Blueprint for Health Care Providers Involved in the Treatment and Monitoring of Patients with Pain (FDA Blueprint)
9. Opioid Analgesic REMS Program website (www.opioidanalgesicrems.com)
Appendix A: List of Professional Societies

1. American Academy of Addiction Psychiatry
2. Council of Medical Specialty Societies
3. Academy of Integrative Pain Management
4. Academy of Managed Care Pharmacists
5. American Academy of Family Physicians
6. American Academy of Hospice and Palliative Medicine
7. American Academy of Neurology
8. American Academy of Nurse Practitioners
9. American Academy of Nursing
10. American Academy of Orofacial Pain
11. American Academy of Pain Medicine
12. American Academy of Physical Medicine and Rehabilitation
13. American Academy of Physician Assistants
14. American Association of Colleges of Nursing
15. American Association of Colleges of Osteopathic Medicine
16. American Association of Poison Control Centers
17. American Board of Medical Specialties
18. American Board of Orofacial Pain
19. American College of Clinical Pharmacy
20. American College of Nurse Midwives
21. American College of Nurse Practitioners
22. American College of Osteopathic Family Physicians
23. American College of Physicians
24. American College of Rheumatology
25. American Dental Association
26. American Dental Education Association
27. American Medical Association
28. American Medical Directors Association
29. American Nurses Association
30. American Nurses Credentialing Center
31. American Osteopathic Association
32. American Osteopathic Association of Addiction Medicine
33. American Pain Society
34. American Pediatric Association
35. American Pharmacists Association
36. American Psychiatric Nursing Association
37. American Society for Pain Management Nursing
38. American Society of Addiction Medicine
39. American Society of Anesthesiologists
40. American Society of Consultant Pharmacists
41. American Society of Pain Educators
42. Association of American Medical Colleges
43. Doctors of Nursing Practice
44. Gerontological Nursing Association
45. Hospice and Palliative Nurses Association
46. National Association of Managed Care Professionals
47. National Association of Pediatric Nurse Practitioners
48. National Conference of Nurse Practitioners
49. National League of Nursing
50. National Organization of Nurse Practitioner Faculties
51. Nurse Practitioners in Women’s Health
52. Oncology Nursing Society
53. Society of Emergency Medicine Physician Assistants