Activity Outline
FDA Drug Topics: Overview of Risk Evaluation and Mitigation Strategies (REMS) for Health Care Providers
June 22, 2021
FDA

Activity Coordinator:
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Series Description

FDA's Division of Drug Information in the Center for Drug Evaluation and Research (CDER) sponsors a series of educational webinars targeting the needs of health care professionals and students. The webinars cover a broad range of FDA drug regulation and medication safety topics. These focused webinars support FDA's mission of promoting and protecting public health through interaction and education to strengthen current and future partnerships and relationships with clinicians and researchers.

Lecture Description
This webinar will provide an overview of REMS and discuss how the REMS safety requirements impact prescribers, dispensers and patients. Participants should gain an understanding of the REMS authorities, how REMS are implemented, and the entities that provide oversite and support. REMS is a drug safety program that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. REMS are designed to reinforce medication use behaviors and actions that support the safe use of that medication. While all medications have labeling that informs health care stakeholders about medication risks, only a few medications require a REMS.

References

- Title 21-FOOD AND DRUGS 21 USC335-1 Risk evaluation and mitigation strategies. https://uscode.house.gov/view.xhtml?req=%28title:21%20section:355-1%20edition:prelim%29%20OR%20%28granuleid:USC-prelim-title21-section355-1%29&f=treesort&edition=prelim&num=0&jumpTo=true. Accessed April 25, 2021.
- FDA Website: Approved Risk Evaluation and Mitigation Strategies (REMS). https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm. Accessed April 25,2021.
- FDA Website: REMS Resources. https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rem s Accessed April 25, 2021.

Series Objectives

- Explain how to utilize FDA's Drug Information, medication safety resources, and regulatory guidances to improve delivery of patient care and optimize outcomes.
- Describe and inform health care providers of recent labeling, policy and regulatory changes which would impact prescribing and medication management to optimize patient care.

Learning Objectives After completion of this activity, the participant will be able to:

- Describe when the FDA can require a REMS.
- List the different elements of Risk Evaluation Mitigation Strategies.
- Identify REMS resources available to healthcare professionals.
- Discuss the possible enforcement actions by the FDA.

Target Audience
This activity is intended for physicians, pharmacists, pharmacy technicians, nurses, Certified Public Health (CPH), and physician assistants.

Agenda

Lecture 1 June 22, 2021

Time	Topic	Speaker
1:00 - 2:00 PM	Overview of Risk Evaluation and Mitigation Strategies (REMS) for Health Care Providers	Cynthia LaCivita, PharmD Dipti Kalra

Continuing Education Accreditation

In support of improving patient care, FDA Center for Drug Evaluation and Research is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC) to provide continuing education for the healthcare team.

This activity was planned by and for the healthcare team, and learners will receive 1 Interprofessional Continuing Education (IPCE) credit(s) for learning and change.

CME

FDA Center for Drug Evaluation and Research designates this live activity for a maximum of 1.00 *AMA PRA Category 1 Credit(s)™*. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

CPE

This knowledge-based activity has been assigned ACPE Universal Activity Number JA0002895-0000-21-037-L04-P, and ACPE Universal Activity Number JA0002895-0000-21-037-L04-T for 1.00 contact hour(s).

CNE

FDA Center for Drug Evaluation and Research designates this activity for 1.00 contact hour(s).

AAPA

This activity is designated for 1.00 AAPA Category 1 CME credits. FDA Center for Drug Evaluation and Research has been authorized by the American Academy of PAs (AAPA) to award AAPA Category 1 CME credit for activities planned in accordance with AAPA CME Criteria. PAs should only claim credit commensurate with the extent of their participation.

CPH

Up to 1.00 CPH Recertification Credits may be earned at this event.

Requirements for Receiving CE Credit

Physicians, physician assistants, pharmacists, nurses, pharmacist techs, and those claiming non-physician CME:participants must attest to their attendance and complete the final activity evaluation via the CE Portal (ceportal.fda.gov). For multi-day activities, participants must attest to their attendance and complete the faculty evaluation each day. Final activity evaluations must be completed within two weeks after the activity - no exceptions.

Attention Pharmacists and Pharmacy Techs: Failure to provide your correct NABP AND Date of Birth information, in the required format, may result in the loss of credit for this activity. NABP profile number should be the 6-7 digit profile number assigned by the CPE Monitor and your birth date should be in the MMDD format (e.g. 0721) Do not provide your pharmacy license number. Please click the "My Account" tab and then navigate to "Edit Contact Information" to verify that your information is correct.

Important Note regarding completion of evaluations and receiving credit
Attendees have 14 days from the last day of the activity to log in, complete the required evaluation(s) and attest to your attendance to claim credit.Physicians, physician assistants, and nurses may then view/print statement of credit. Pharmacists should log into the CPE monitor 8 weeks after the last session of the activity to obtain their CE credit.

Disclosure

Faculty

- Kalra, Dipti, safety evaluator, FDA *nothing to disclose*
- LaCivita, Cynthia, PharmD, Director, Division of Risk Management, FDA *nothing to disclose*

Planning Committee

- Burke, Kara, PharmD, Team Leader/Pharmacist, FDA/CDER/OCOMM/DDI *nothing to disclose*
- Cao, Christian, MPAS, PA-C, Safety Evaluator Team Leader, FDA/CDER/OSE/DPV *nothing to disclose*
- DeFronzo, Kimberly, RPh, MS, MBA, Consumer Safety Officer, FDA/CDER/OCOMM/DDI *nothing to disclose*
- Kapoor, Rama, MD, Medical Officer, FDA *nothing to disclose*
- Navin, Lesley, RN, MSN, Consumer Safety Officer, FDA/CDER/DDI *nothing to disclose*
- Nguyen-Chu, Thanh Tam, PharmD, Pharmacist, FDA/CDER/OCOMM/DDI *nothing to disclose*
- Paraoan, Dianne, MPH, RN, Associate Director for Regulatory Affairs, FDA/ CDER/ OMP *nothing to disclose*

CE Consultation and Accreditation Team

- Bryant, Traci, M.A.T., CE Consultant, FDA/CDER/OEP/DLOD - nothing to disclose
- Zawalick, Karen, CE Team Leader, FDA/CDER/OEP/DLOD - nothing to disclose

Registration Fee and Refunds

Registration is complimentary, therefore refunds are not applicable.