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REMS Strategies: Successful Management

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Jason R. Bailly

Specialty Pharmacy Operations Manager

UC San Diego Health

Lisa Cristofaro

Market Access Manager, Specialty Pharmacy

University of Rochester Medical Center

Burnis D. Breland

Regional Account Director

Acentrus Specialty

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Disclosure

The following individuals report having no relevant conflicts of interest:

- Jason R. Bailly
- Lisa Cristofaro
- Burnis D. Breland

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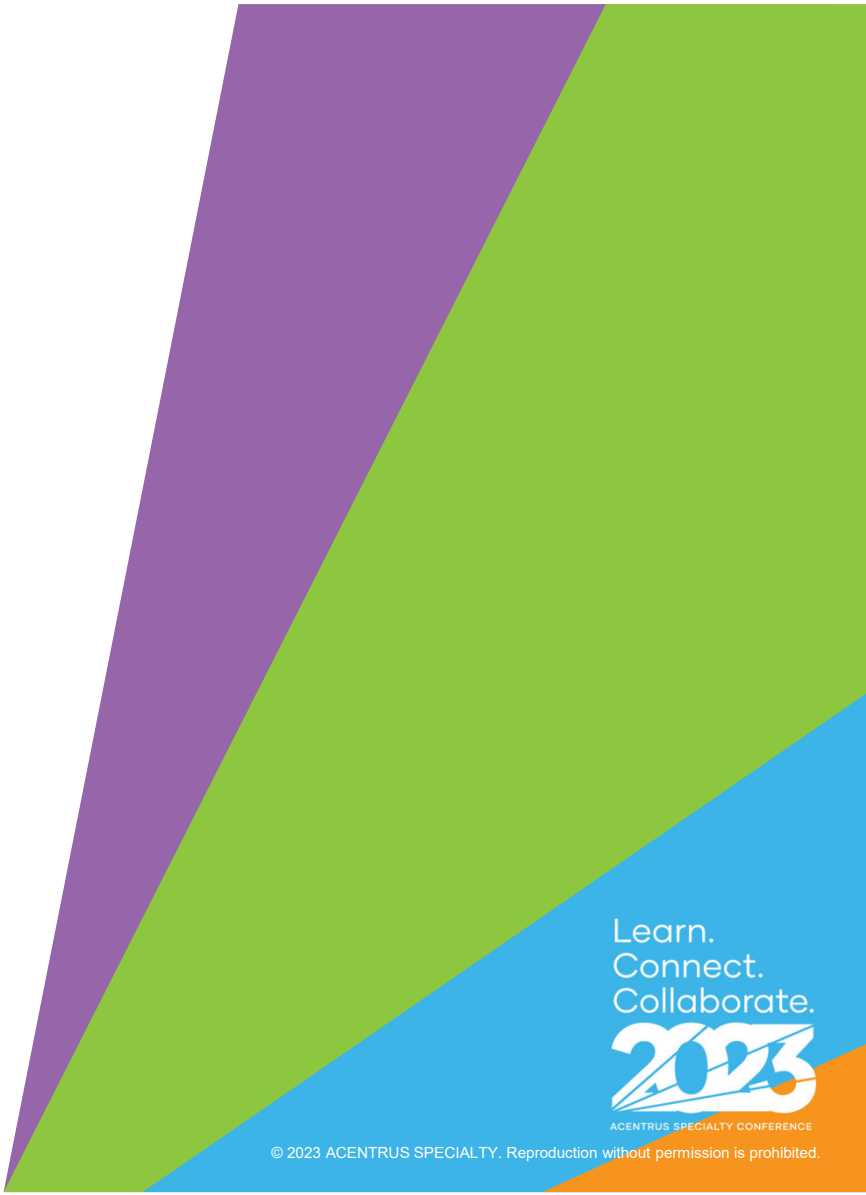
Learning Objectives

1. Describe the FDA REMS program and how it affects the dispensing of specialty medications that have REMS requirements
2. Discuss the various operational processes involved in implementing procedures within a health system specialty pharmacy to meet REMS requirements for specialty medications
3. Describe solutions to various challenges in dispensing REMS specialty medications, including documentation of patients' testing requirements, establishing systems for patient monitoring, and reporting of required data to the manufacturer and FDA



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Risk Evaluation and Mitigation Strategy (REMS) Program

Program Overview

- **FDA Risk Minimization Action Plans (RiskMAPs)**

  Resulted from adverse drug events: VIOXX (rofecoxib) in 1999, and later ACCUTANE (isotretinoin), TIKOSYN (dofetilide), TRACLEER (bosentan), PLENAXIS (abarelix)

- **FDA Amendments Act of 2007 expanded FDA authority to authorize the REMS program**

  "A drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks"

- **FDA may require med guide or patient package insert, communication plan, and/or elements to assure safe use (ETASU)**

  ETASU may include certification requirements, patient enrollment registries, limited distribution plans, certifications, and medical interventions or actions providers must take

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What REMS drugs are health system specialty pharmacies (HSSPs) dispensing?

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What REMS drugs are health system specialty pharmacies (HSSPs) dispensing?

- **REMS drugs sometimes dispensed by HSSPs include ambrisentan, vigabatrin, SILIQ (brodalumab), SUBLOCADE (buprenorphine extended-release), TEGSEDI (inotersen), REVLIMID (lenalidomide), TRACLEER (bosentan), and others**
- **FDA currently has 61 drugs with REMS requirements**
  - https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems
  - On December 17, 2021, FDA launched a public dashboard for medications with an approved REMS: the REMS Public Dashboard
- **REMS requirements are different for each drug: ETASU, communication plans, and others**
- **Not all REMS drugs have a pharmacy requirement—e.g., GATTEX (teduglutide)**
- **New REMS added in 2022 and 2023 include CAMZYOS (mavacamten), CARVYKTI (ciltacabtagene autoleucel), TECVAYLI (teclistamab-cqyv), and FILSPARI (sparsentan)**

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What challenges do HSSPs face in meeting REMS requirements?

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What challenges do HSSPs face in meeting REMS requirements?

- **Workload, complexity, consistent accuracy, information sources, documentation, data reporting**
- **Conduct a pharmacy risk assessment**
- **REMS policy required**
  - Include REMS drugs as high-risk medications
  - May develop SOP for each REMS drug; others use workflow documents to guide activities
- **Adhere to specialty pharmacy accreditation requirements for handling REMS drugs**
- **Determine pharmacy/organization authorizing representative and REMS point person**
- **Recognize differences in requirement for inpatients and outpatients (e.g., ambrisentan)**
  - Consider transition of care (provide advance notice to outpatient pharmacist to plan discharge)
- **Assure manufacturer that HSSP can meet all REMS requirements, including reporting**
- **Data requirements**

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How do HSSPs meet REMS reporting requirements?

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How do HSSPs meet REMS reporting requirements?

- **Patient intake and processing the prescription; ensuring all REMS requirements are met**
  - Not all data may be available in the pharmacy system
- **Patient care and dispensing data may be required by the FDA and/or the manufacturer**
  - Data transmissions are different for each drug
  - May require multiple data feeds and different time intervals for reporting (weekly to <hourly)
- **Build out the care plan within the patient care management system (e.g., Epic) using customized smart forms**
- **Build the data capture and data submission process**
  - Analytics teams build out the process to send data to UBC (e.g., ambrisentan, vigabatrin) or contract with a third party to submit data to UBC
  - Extensive customization may be required (e.g., reporting dispense status data with vigabatrin)
  - UBC reporting process: requires a business associate agreement (BAA), data testing, data validation and approval
  - Manufacturer may require submission of paper report forms
- **Hard to pivot to a different manufacturer if generic drug unavailable from primary source**

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How do HSSPs provide REMS training to staff to ensure consistent accuracy?

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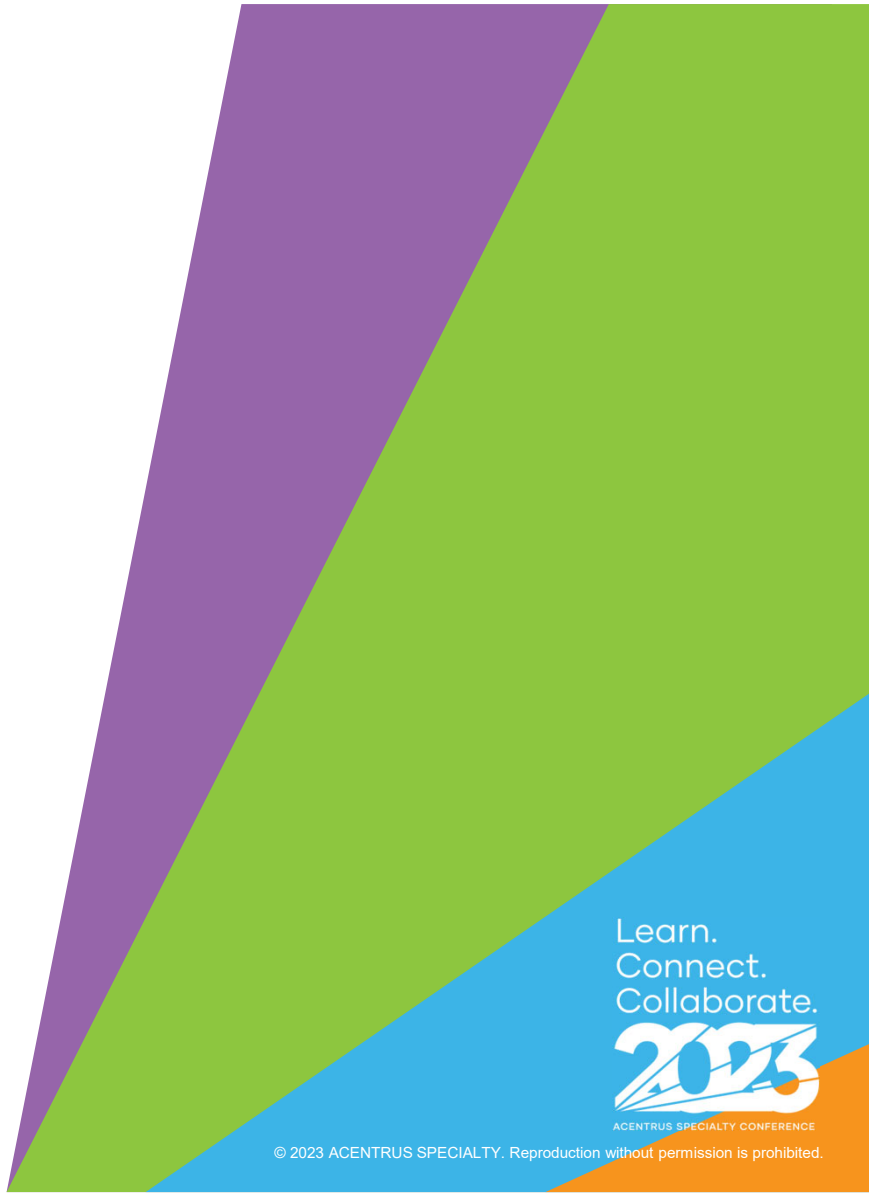
How do HSSPs provide REMS training to staff to ensure consistent accuracy?

- Establish training policy for REMS drugs
- Describe handling procedures unique to each drug
- Provide training sessions for staff; specify at least annual training updates
- Validate staff competence to ensure compliance
- Develop training to accommodate staff cross-coverage



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How do you document REMS activities?

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How do you document REMS activities?

- **Documentation and record keeping; generating reports**
- **Quality and monitoring of compliance**
  - Checklists are helpful to ensure compliance
- **Audits**
  - Can be long and arduous
  - Consequences of errors are significant
  - Removal from the REMS program may result

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Take-Home Thoughts

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Questions

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