Risk Evaluation and Mitigation Strategies (REMS) program optimization within an integrated health system specialty, retail, and home infusion pharmacy

Lena Evangelista, PharmD, BCPS; Alexa Risser, PharmD; Kimberly Tynik, PharmD, CSP, PRS; Terri Sue Rubino, PharmD, CSP;
Katie Laskin, PharmD, BCSCP, FNHIA, CNSC; Vinay Sawant, RPh, MPH, MBA

Background

- Risk Evaluation and Mitigation Strategies (REMS) are FDA-required programs designed for medications with serious safety concerns that cannot be adequately managed through the prescription labeling information alone.
- REMS programs support safe medication use by ensuring that the benefits of a medication outweigh its risks through specific requirements, as well as ongoing monitoring and education.
- Compliance with REMS requirements is critical to supporting safe medication use.
- There are currently 74 total available REMS programs.
- Yale New Haven Health pharmacies are enrolled in 19 REMS programs, and each program has requirements for patients, providers, pharmacies, and/or healthcare settings.
- Integrated pharmacy services include one specialty pharmacy, one home infusion pharmacy, and four retail pharmacy locations. Inpatient and ambulatory pharmacy services were excluded.

Objective

To standardize and optimize REMS program management across Yale New Haven Health integrated pharmacy services through standardization, education, and enhanced oversight.

The rationale for this project included:

- Absence of written procedures surrounding REMS programs
- Lack of standardization for organization of documents and succession planning
- Gap in pharmacy staff training

Methods

Gap Analysis

- Reviewed all FDA REMS programs and created a comprehensive reference document for all active REMS programs.
- Evaluated electronic pharmacy dispensing system REMS flags for accuracy and effectiveness.
- Assessed enrollment status in REMS programs.

Implement

- System-wide standard operating procedure (SOP) outlined.
- Annual training and education modules developed for medications dispensed.

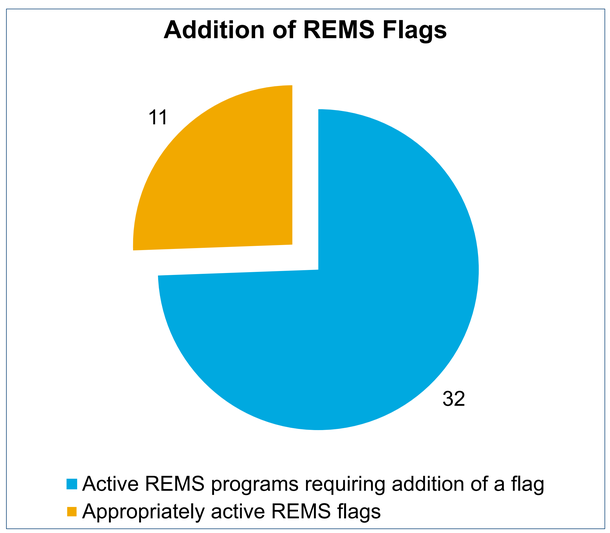
Results

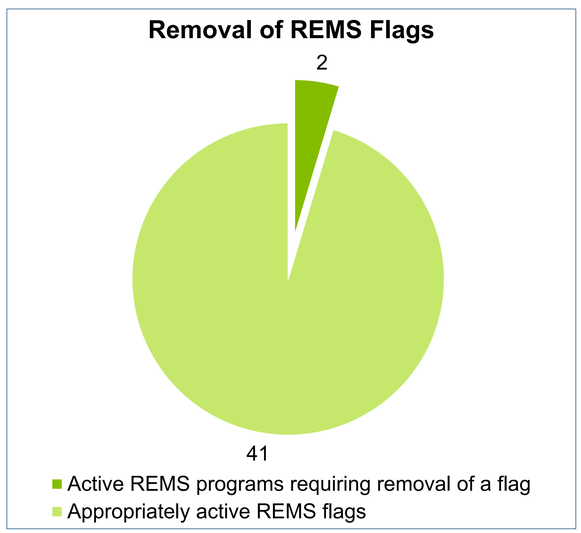
The project achieved several significant operational improvements:

- Review of organizational REMS enrollments revealed discrepancies requiring corrective action.
- REMS program documentation was collected from pharmacy managers and centralized into a standardized database.
- Existing REMS medication flags within the electronic dispensing system were reviewed, and opportunities were identified to add, modify, or remove flags based on current FDA requirements.
- A comprehensive REMS reference document covering all active FDA REMS programs was developed.
- A department-wide REMS Standard Operating Procedure (SOP) was developed, approved, and distributed to pharmacy staff.
- Annual REMS training modules were completed for home infusion pharmacy staff, with retail and specialty pharmacy training development ongoing.

Evaluation of Current REMS Program Enrollment

Location	Existing	Newly Identified
Specialty Pharmacy	11	1
Home Infusion Pharmacy	6	0
Retail Pharmacy 1	4	1
Retail Pharmacy 2	5	1
Retail Pharmacy 3	5	2
Retail Pharmacy 4	4	2
Total	**35**	**7**





Discussion

Measures of Success

Threshold	Target	Stretch/Maximum
• REMS information gathering from REMS FDA website and pharmacy managers	• Create SOP • Updated REMS reference document • Identified all areas of noncompliance	• All flags in place • Finalized SOP • Rectify all areas of noncompliance • Develop training modules for specialty and retail sites

Lessons Learned

The team learned that REMS requirements are complex and frequently updated, necessitating ongoing monitoring and maintenance. Standardization across multiple pharmacy practice settings is essential to achieving consistent compliance. Centralized documentation improves regulatory readiness and reduces variability between locations. Electronic dispensing system alerts and flags require periodic review to remain aligned with current FDA requirements. Staff education and clearly defined workflows are critical components of sustainable REMS compliance. Cross-functional collaboration among clinical, regulatory, quality, and operational teams enhances project success and implementation.

Impact on the Patient Experience

The optimization of REMS processes directly supports a safer and more consistent patient experience by ensuring required safety measures are completed prior to medication dispensing.

Patient-centered benefits include:

- Improved medication safety through adherence to FDA-mandated risk mitigation requirements.
- Reduced risk of errors associated with incomplete REMS documentation or enrollment.
- More consistent communication regarding medication-specific risks, monitoring requirements, and patient responsibilities.
- Enhanced continuity of care across specialty, retail, and home infusion pharmacy settings.

Conclusion and Future Directions

Strengthening REMS processes and compliance is critical to ensure safe medication use practices and the protection of patients, prescribers, and pharmacies from preventable risk. Ongoing efforts will support the implementation of standardized processes and sustainable workflows to maintain long-term REMS compliance across all integrated health system pharmacy locations.

FDA REMS programs are constantly changing, requiring the deliverables to be manually updated moving forward.

The authors of this presentation have nothing to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation.

NASP Annual Meeting & Expo 2026. Sept 22-25, 2026.