Mavacamten REMS Management Process Improvement Strategy

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BACKGROUND

- Cardiac myosin inhibitors, including mavacamten, have dedicated REMS (Risk Evaluation and Mitigation Strategy) Programs regulated by the U.S. Food & Drug Administration.
- The specific objectives of the mavacamten REMS program are to monitor for detection of heart failure due to systolic dysfunction with periodic echocardiograms and to screen for drug interactions prior to each dispense.
- To meet the mavacamten REMS program requirements, pharmacist involvement is necessary to complete patient counseling, screen for drug interactions, certify documentation in the REMS program portal, perform product verification, and facilitate time-sensitive dispensing.
- Additional pharmacist documentation is utilized in the electronic medical record (EMR) per our pharmacy's standard operating procedure to standardize data sharing, maximize clinical accountability, and promote collaboration across the care team.
- Our prior process involved individual patient assignments to specific pharmacists and tracking assignments outside of the EMR on a shared spreadsheet.
- Exponential patient growth (from 5 to > 70 patients) necessitated a streamlined workflow to improve pharmacist engagement, maintain comprehensive EMR documentation, and promote clinical efficiency.

PURPOSE

Identify areas for optimization in the current mavacamten REMS workflow and assess baseline pharmacist satisfaction.

Adapt processes to incorporate measurable clinical tasks and standardized EMR documentation.

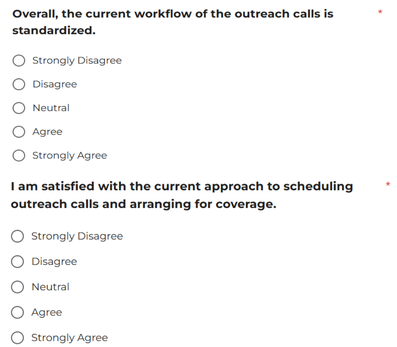
Reengage pharmacists to accommodate further patient volume while utilizing a scalable management approach.

METHODS

Assess Current Workflow → Optimize Organization → Optimize Documentation → Implementation of Workflow

Survey Collection

- A survey was created to address the current workflow.
- The survey assessed the current organization, scheduling, standardization, value of documentation, ease of use, time required, and pharmacist satisfaction with the process.

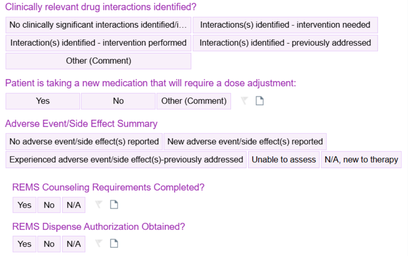


Creation of REMS Service Line

- This service line was created within our existing EMR-integrated care coordination and workflow management software.
  - Patient enrollment in this service line facilitates the scheduling of clinical activities at appropriate times by utilizing a customized report.
  - Monitoring the service line and its reporting provides visibility into upcoming workloads and patient volumes.
  - The REMS Service line captures pharmacist interventions in a measurable way through completion of REMS Outreach Assessments.

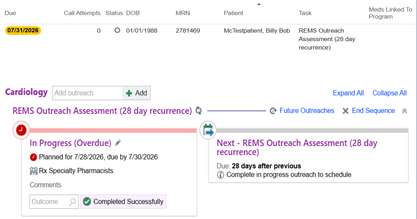
Creation of REMS Outreach Assessment Flowsheet

- A standardized assessment was created to easily document what is being evaluated in each outreach while incorporating and highlighting the REMS Program requirements.
  - The REMS Assessment task utilizes a custom flowsheet which, when coupled with a clinical note template, auto-populates the data from the flowsheet into a standardized EMR documentation with just a few keystrokes.
  - The subsequent creation of the clinical note allows for ease of visibility in the EMR across all teams.



Train Pharmacists on New Workflow

- All eligible patients were enrolled into the REMS service line and assigned follow-up dates based off their last refill.
- Pharmacists were assigned weekly rotations to run and review the new report to see which patients were due for assessment and contact them proactively.
- Individual training on the report, completing the flowsheet, and prompting the creation of the clinical note was provided for each pharmacist to ensure a seamless transition from the old process to the new.



FUTURE DIRECTIONS

- Monitor patient volume through completion of pharmacist outreach assessments to evaluate the impact of the REMS program on specialty pharmacy workflow.
- Measure pharmacist satisfaction with updated process utilizing a post-intervention survey after 2 cycles through new workflow.
- Utilize this REMS management process for other/future medications with REMS Program requirements.

REFERENCES

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