



In Workflow Best Practices for Automating REMS – NCPDP Session 3

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Challenges with REMS

REMS often require prescribers to meet certain safe use conditions:

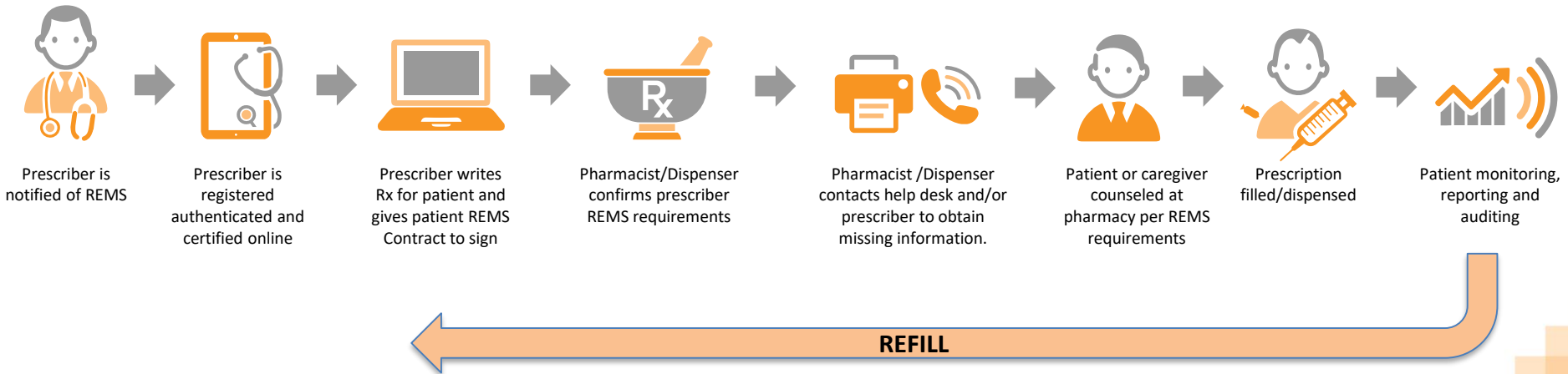
- Be enrolled and trained
 - Counsel and monitor patients
 - Prescribe the medication only under certain conditions
- Currently, many REMS do not provide prescribers with a simple, standardized way to tell whether safe use conditions are met

Patient Frustration and Potential Delay in Therapy

Patients often discover they are unable to receive a drug when they appear at the pharmacy

Issues that could have been resolved in the prescriber's office are left to the pharmacist

Current REMS Process: Physician, Patient and Pharmacist



Burdensome manual process completed through phone, fax and portals which may lead to delay in therapy

Goals of REMS Automation



Maximize

- Efficiency
- Patient access
- Prescriber participation & benefits
- Satisfaction of FDA



Minimize

- Cost
- Disruption of existing workflows
- Liability
- Risk of failure



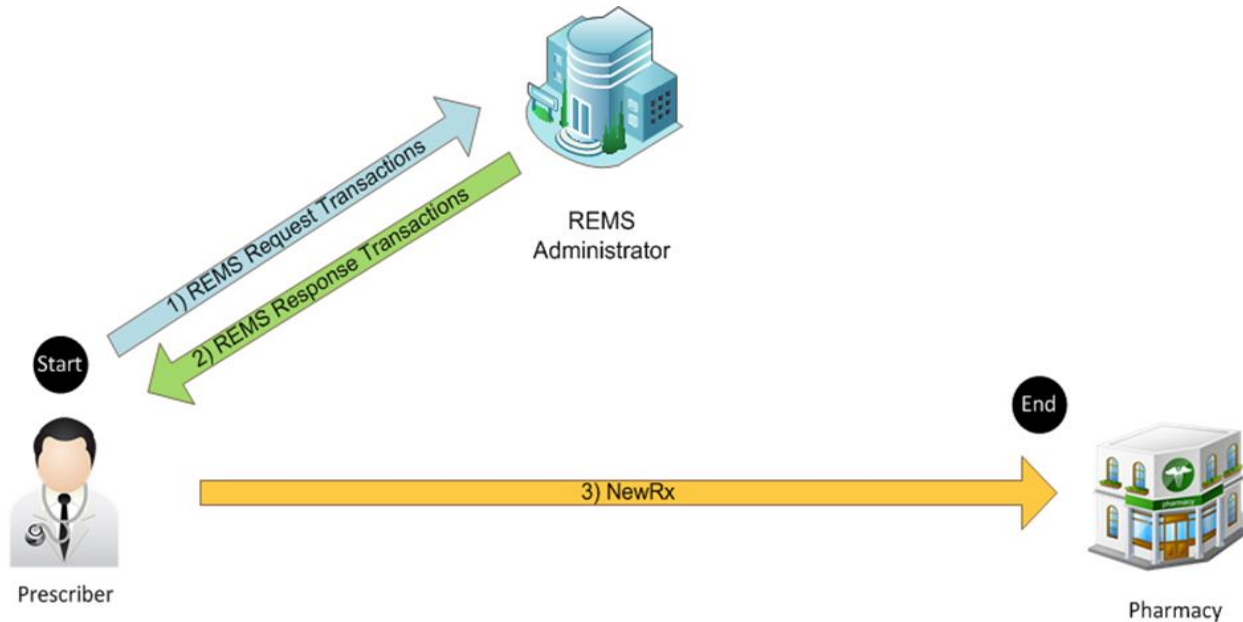
Current REMS Transactions

- Transaction implementation guide for REMS Transaction for pharmacies and pharmacy systems released in 2011
 - Allows pharmacies to use **NCPDP** claims transaction to **electronically confirm that REMS requirement has been met and pharmacy can dispense the medication**
 - Currently not a “named” standard in legislation, but pharmacies and intermediaries implemented the transaction through trading partner agreements
- **NCPDP** ePrescribing transaction updated to include REMS transaction in 2016
 - Provides **prescribers with a simple, standardized solution to help prescribers meet safe use conditions and ensure patient access**
 - Notify prescribers on REMS requirements at point of prescribing and helps resolve issues prior to Rx arriving at pharmacy
 - Transaction “named” in regulation through CMS

Automating REMS in an EHR.



REMS Transaction for Providers



REMS transactions are triggered through SPL and exchanged as other standard transactions, in a real-time request and response mode



Automating REMS in a Pharmacy

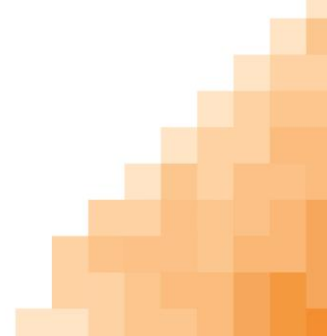
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Automating Pharmacy REMS Authorization

Review of the industry problem:

- 50% of the drug pipeline are biologics/specialty drugs
 - Many require therapy cycle specific REMS actions including:
 - Dispensing with Med Guides
 - Data Collects/Lab value evaluation
 - Surveys/Assessments
 - Dispense Confirmation / Authorization
 - Manual processes to administer these requirements



Automating Pharmacy REMS Authorization

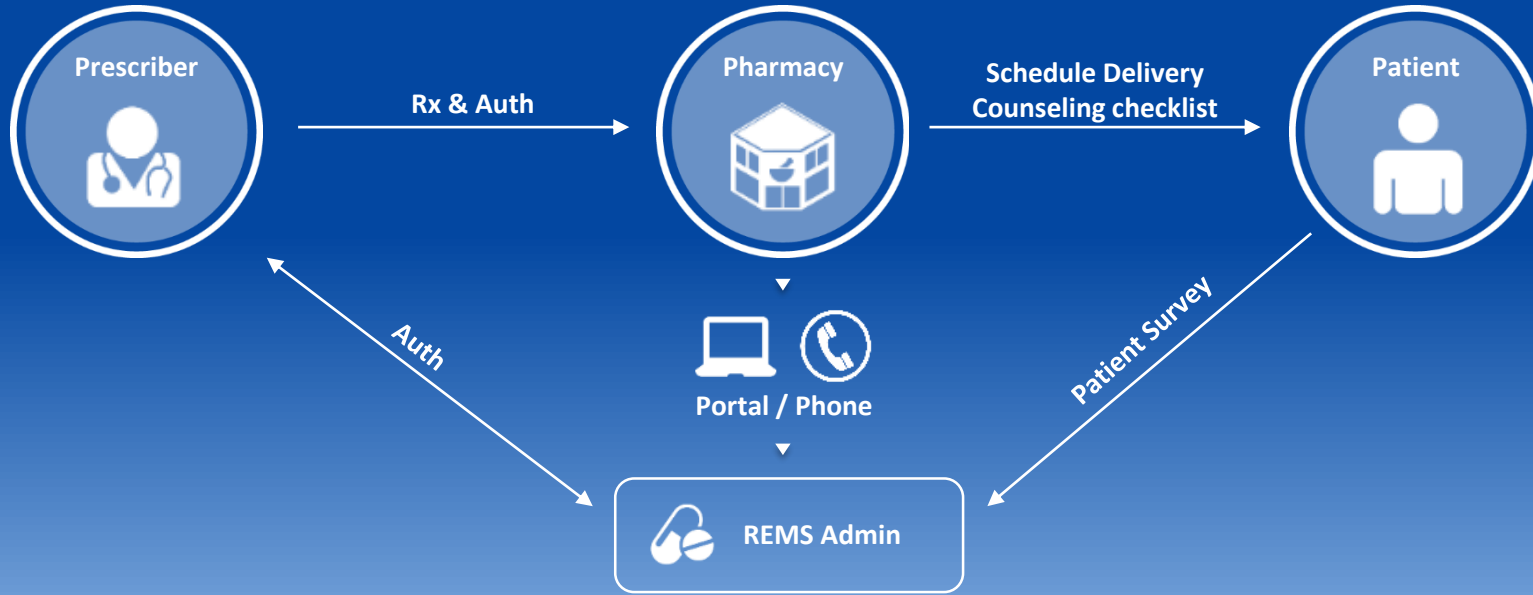
Use Case

- Physician prescribes a strict REMS drug for an oncology patient
- Pharmacy receives the prescription and must initiate the processes needed to support the REMS requirements
 - Requires manual use of Pharma Portal





Existing Workflow




Automating Pharmacy REMS Authorization

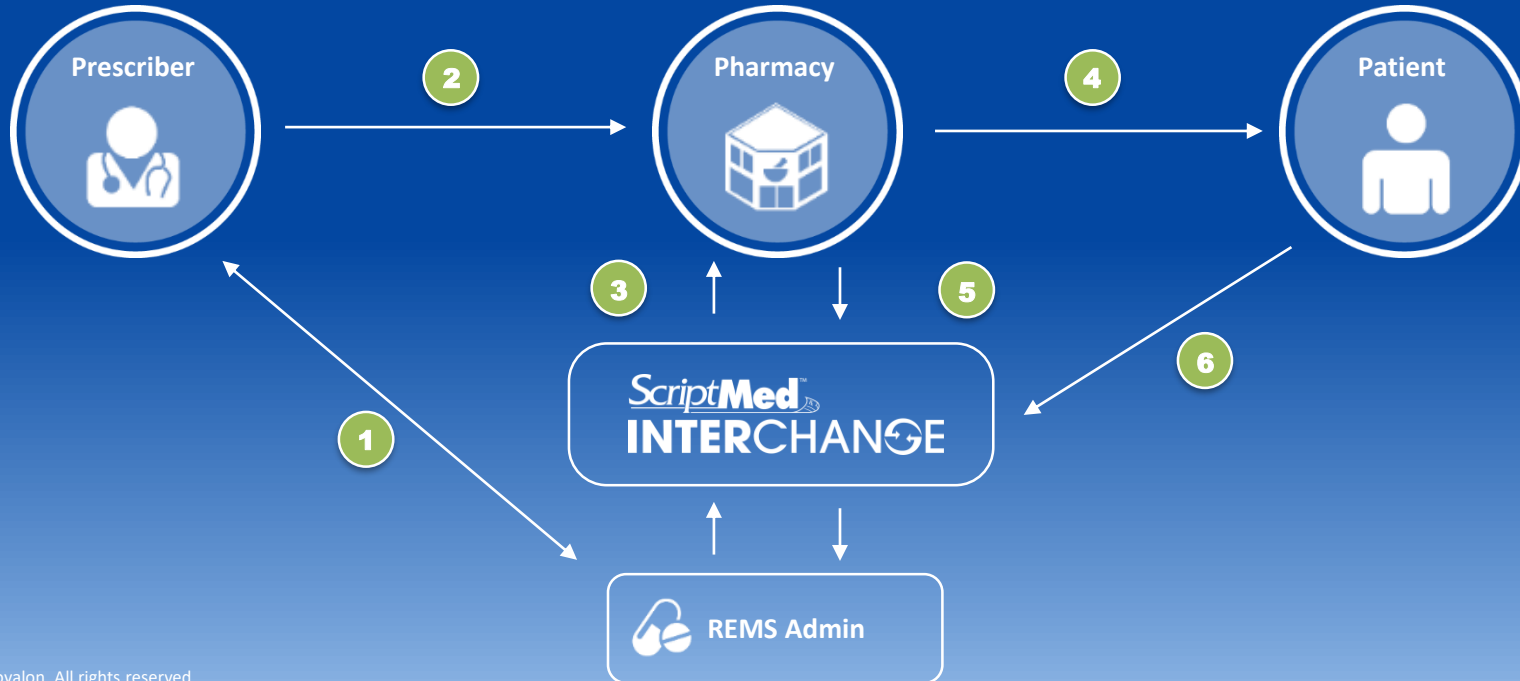
Real World Solution

- Established a partnership with a Pharma to:
 - Develop custom API to replace manual process with bi-directional synchronous interface
 - Validate Dispense Auth
 - Obtain Ship Confirmation

Solution value propositions

- Decrease time to fill
 - Realize measurable operational labor savings
 - Increase data entry accuracy and decrease data re-entry of errors
 - Accuracy of data reporting
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Automated Workflow



Automating Pharmacy REMS Authorization

Key Objectives / Challenges:

Complete replacement for Portal

Including solving for all responses

- Success
- Rejection
- Additional follow up required

Improve Data Validation between Prescriber and Pharmacy

Support FDA approval process

- Manual daily audit during Pilot
- Formal FDA review and approval



Automating Pharmacy REMS Authorization

Project Success Metrics:



Increase Speed to Therapy



Decrease Cost to Fill




Improved Accuracy



Effort to dispense REMS drug same as other specialty drugs

Automating Pharmacy REMS Authorization

Observations and Conclusions:

- Well defined problems easier to solution
 - Extending existing capabilities improves time to market
 - Determining the finite outcomes of data exchange key to eliminating manual exceptions
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Q&A



Automating REMS in an EHR.

