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Building a Common Risk Evaluation and Mitigation Strategies (REMS) Platform

June 7, 2016

Introduction to the REMS Integration Initiative

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FDA, CDER

Outline

- Background on Risk Evaluation and Mitigation Strategies (REMS)

- Introduction to the REMS Integration Initiative
  - Stakeholder outreach
  - PDUFA V commitments
  - Priority projects

- The future of the REMS Integration Initiative

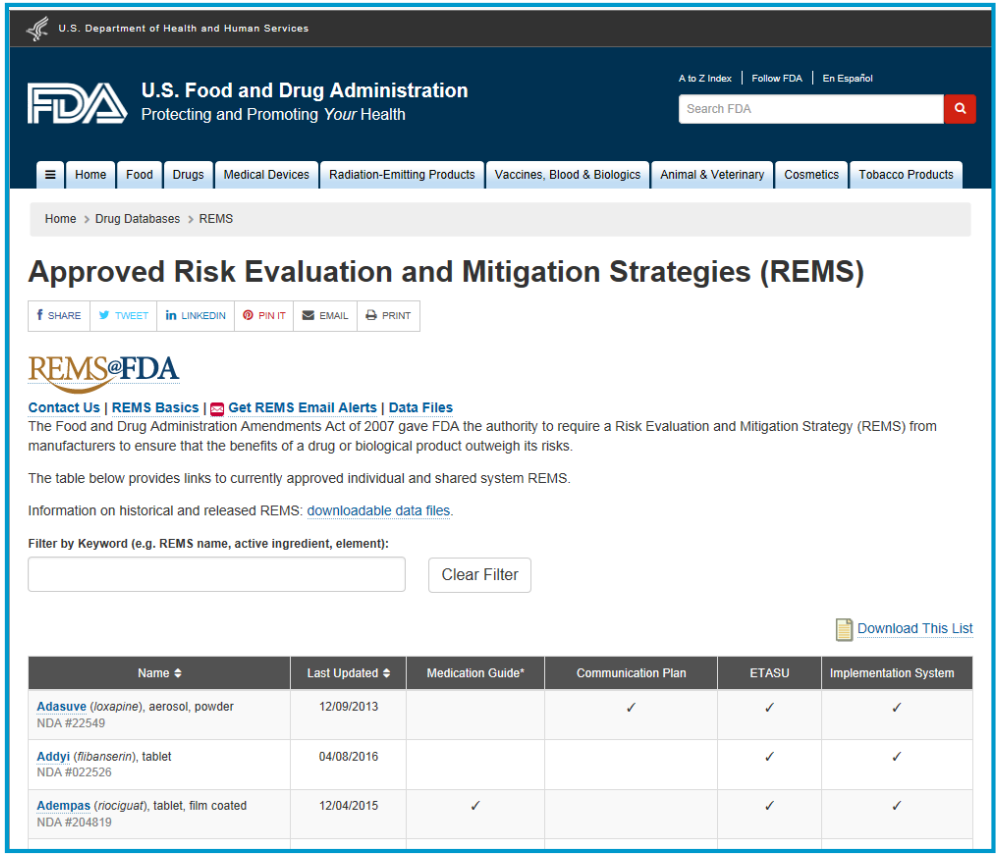
Background: REMS

- A REMS is a risk management plan using risk minimization strategies beyond FDA-approved FDA professional labeling to **mitigate a specific risk or risks of a drug.**

- The FDA Amendments Act (FDAAA) of 2007 authorizes FDA to require a REMS if the FDA determines that a REMS is **"necessary to ensure the benefits of the drug outweigh the risks"**
  - Pre-approval
  - Post-approval (if new safety information arises necessitating it)

Background: REMS

- A REMS may include one or more of the following:
  - Medication Guide or Patient Package Insert (PPI)
  - Communication Plan for Healthcare Providers (HCPs)
  - Elements to Assure Safe Use (ETASU)
  - Implementation System
- A REMS must include a Timetable for Submission of REMS Assessments for NDAs/BLAs



Background: ETASU REMS

- Elements to Assure Safe Use (ETASU) are required medical interventions or other actions healthcare professionals need to execute prior to prescribing or dispensing the drug to the patient
- Some actions may also be required in order for the patient to continue on treatment

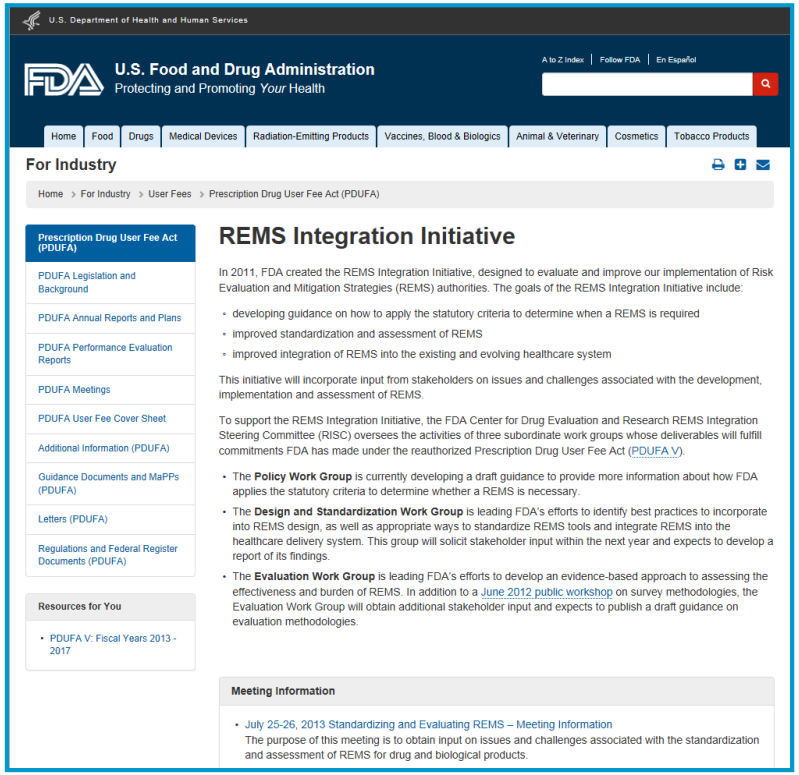
ETASU requirements are the most extensive elements of a REMS program.

Background: ETASU REMS

ETASU can include:

- Certification and specialized training of prescribers
- Certification of pharmacies or other dispensers of the drug
- Dispensing/administration of drug in limited settings (e.g., hospitals)
- Dispensing/administration of drug only with evidence of safe use conditions
- Patient monitoring
- Enrollment of treated patients in registries

The REMS Integration Initiative



In 2011, FDA created the REMS Integration Initiative, designed to evaluate and improve implementation of REMS authorities.

The goals of the REMS Integration Initiative include:

- Developing guidance on how to apply the statutory criteria to determine when a REMS is required
- Improved **standardization** and assessment of REMS
- Improved **integration** of REMS into the existing and evolving healthcare system

Key Components of the REMS Integration Initiative

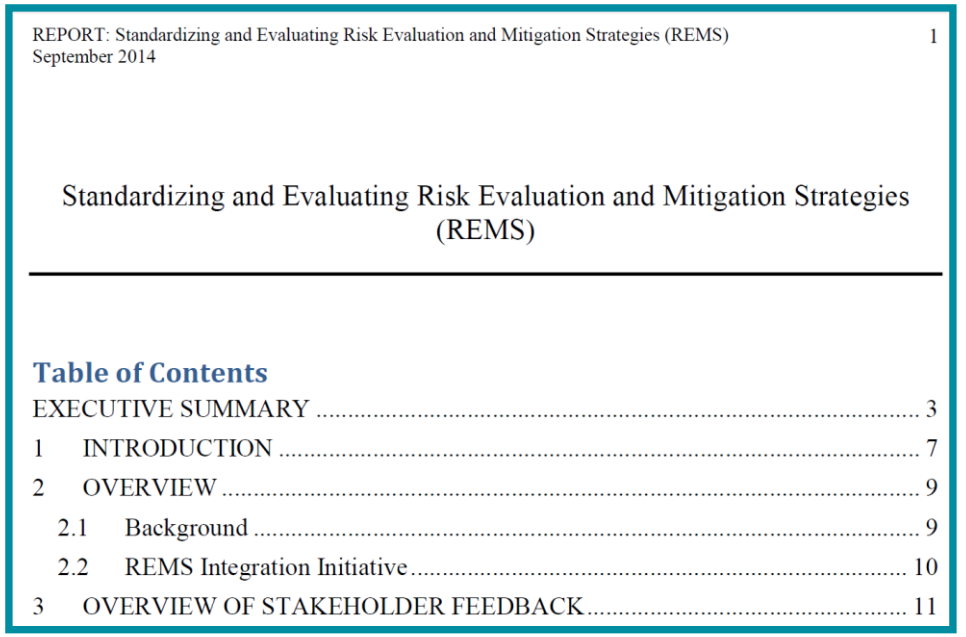
- Stakeholder outreach to better understand how existing REMS programs are working and where opportunity for improvement lie
- Standardization and integration of REMS into existing healthcare practices
- Implementation of REMS commitments included in the 5th reauthorization of the Prescription Drug User Fee Act (PDUFA V)
  - Guidance development
  - 4 priority projects to address specific areas of improvement

Stakeholder Engagement under the REMS Integration Initiative

Date	Meeting
March 8, 2013	PDUFA Stakeholders Meeting (REMS Integration Initiative)
March – June 2013	15 Stakeholder Listening Sessions — Experience Implementing ETASU REMS
May 16, 2013	Drug Safety Board Meeting
May 23, 2013	Trends Emerging in Risk Management (TERM) Meeting
July 25-26, 2013	REMS Standardization and Evaluation Public Meeting
Sept. 25, 2013	Strengthening REMS Through Systematic Analysis, Standardized Design, and Evidence-Based Assessment (Brookings)
Feb. 6/ May 6, 2015	NCPDP Workgroup Meeting and Annual Conference (SPL Priority Project)
Feb. 9, 2015	HL7 SPL Tech Team (SPL Priority Project)
May 18, 2015	Incorporating continuing education into single-drug REMS: Exploring the challenges and opportunities (Brookings-CME Priority Project)
July 25, 2015	Expert Workshop (Brookings-Providing Patient Benefit Risk Information Priority Project)
Oct. 5-6, 2015	Understanding and Evaluating REMS Impact on the Health Care Delivery System and Patient Access (Common REMS Platform Introduced)
April 14, 2016	Expert Workshop (Duke-Providing Patient Benefit Risk Information Priority Project)
Dec. 2015 – May 2016	REMS SPL Pilot with 9 companies to test & refine the REMS data model/terminology

Report: Standardizing and Evaluating REMS

- Provides an analysis of stakeholder feedback
- Identifies one priority project in the four areas outlined in PDUFA V
- Provides plans for project completion



REPORT: Standardizing and Evaluating Risk Evaluation and Mitigation Strategies (REMS) 1
September 2014

Standardizing and Evaluating Risk Evaluation and Mitigation Strategies (REMS)

Table of Contents

Priority Projects

Topic Areas	Projects Selected	Deliverable
Providing benefit/risk information to patients	Providing Patient Benefit/Risk Information by Improving Tools for Prescriber-to-Patient Counseling	A report of findings, counseling processes, and tools that could serve as a basis for designing new tools and validating them in demonstration projects
Prescriber Education	Prescriber Education—REMS and Continuing Education (CE) for Health Care Providers	A report on the feasibility of REMS-related CE that will include a description of potential models for REMS-related CE development and delivery
Pharmacy Systems	Standardizing REMS Information for Inclusion into Pharmacy Systems Using Structured Product Labeling (SPL)	Make structured REMS information available to health care providers, patients, and FDA
Practice Settings	Providing a Central Source of REMS Information for Practice Settings	An enhanced FDA REMS Website

Project #1: Benefit Risk Information

- Research and codify best practices in effectively counseling patients about medications' benefits and risks
- Develop a framework of methods, techniques, practices and tools to help guide healthcare providers when counseling patients
  - How to effectively counsel (e.g., technique, modes of communication, timing, confirmation of understanding, etc.)
  - Not what a healthcare provider should say

Status:

- Framework has been developed
- Currently being refined based on stakeholder feedback at a July 2015 Brookings Expert Workshop and April 2016 Duke Expert Workshop

Project #2: Prescriber Education

- Assess the feasibility of incorporating continuing education (CE) into individual REMS programs that include a Communication Plan and/or HCP training
- Define objectives for REMS CE programs
  - articulate approaches to achieving them,
  - examine potential barriers to implementing these approaches, and
  - consider ways to address or overcome these barriers.
- Identify approaches to developing REMS CE that can be implemented, or identify reasons why these approaches are not feasible

Status:

- Stakeholder outreach continues to identify possible approaches to REMS-related CE development

Project #3: Pharmacy Systems

- Structured Product Labeling (SPL) is an HL7 standard used to capture structured information about drug products
- SPL will be used to capture information about REMS (i.e., REMS Documents) in a structured format
- The REMS materials themselves (e.g., training, forms) are not planned to be captured in SPL format

Status:

- Developed a data model and balloted data elements with HL7
- Completed a successful pilot with 9 companies to test and refine FDA's approach to integrating REMS into SPL format

Project #4: Practice Settings

- Enhance the REMS website, providing a centralized, standardized, reliable, and user-friendly repository of information about REMS to:
  - Help stakeholders understand and comply with REMS requirements
  - Minimize confusion associated with complying with multiple REMS programs
  - Provide stakeholders up-to-date and comprehensive REMS information

Status:

- **REMS@FDA** launched on June 15, 2015
- Work continues to refine and update the website based on stakeholder feedback

The Future of the REMS Integration Initiative

- FDA remains committed to improvement of REMS program implementation, informed by stakeholder feedback, and reflecting the dynamic and evolving nature of drug development and healthcare practices.
- Guided by stakeholder feedback and recommendations through a variety of outreach activities, FDA identified the Common REMS Platform Initiative as the next step to further enhancing and improving REMS integration into the healthcare system.

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Building a Common Risk Evaluation and Mitigation Strategies (REMS) Platform

June 7, 2016

Overview the Common REMS Platform

Adam Kroetsch, MSPPM

Building A Common REMS Platform

Duke-Margolis Center for Health Policy

June 7th, 2016

Contents

Why is standardization so important?

Standardizing allows us to…

- Continually improve the quality of REMS design
- Create predictability
- Create positive "network effects"

Standardization is the first step to process improvement and a "quality systems" approach to care.

What are health data standards?

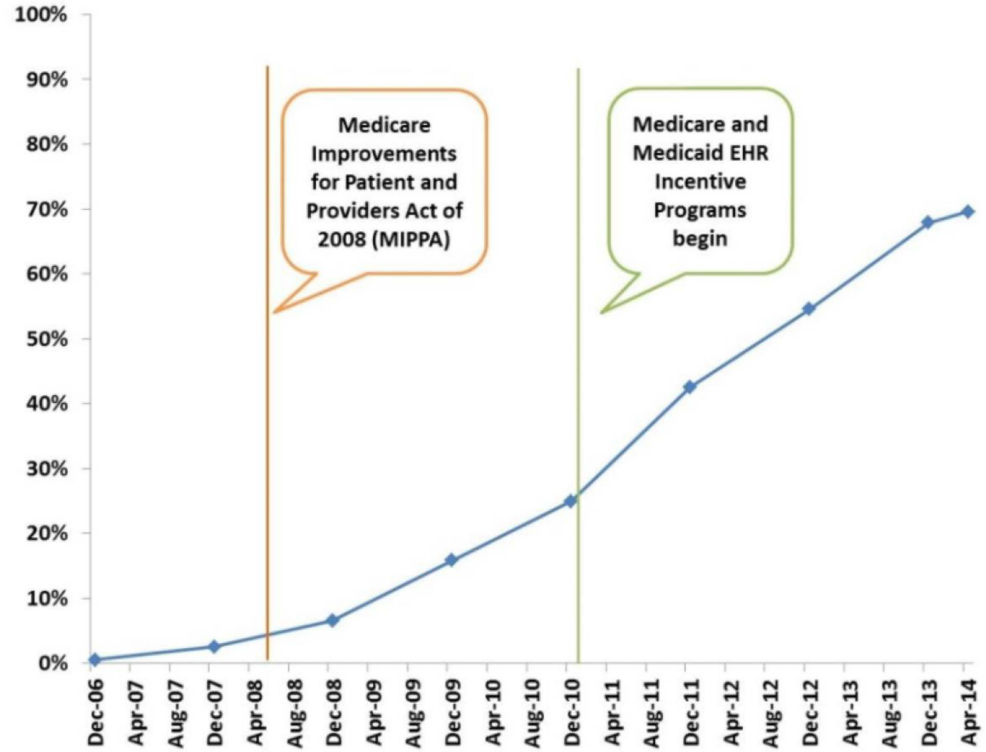
- Standards are a common way of (electronically) communicating health information
- They allow healthcare providers to work together in a large, complex, and increasingly electronic healthcare system.
- They have a couple of distinctive features:
  - Not developed by FDA or government, but rather by Standards Development Organizations (SDOs) like NCPDP[1] and HL7[2]
  - Once they're developed, they need to be adopted by stakeholders (i.e., healthcare providers and REMS programs)

[1]National Council for Prescription Drug Programs
[2]Health Level 7 International

Most REMS have not leveraged health data standards

First REMS was approved in 2008, when less than 10% of prescribers were e-prescribing (now 70% do so)

Percent of physicians e-prescribing using an EHR



Source: E-Prescribing Trends in the United States. Office of the National Coordinator for Health Information Technology (ONC). July 2014. Retrieved from http://www.healthit.gov/sites/default/files/oncdatabriefe-prescribingincreases2014.pdf

Contents

1. Background on Health Data Standards in REMS
2. **Existing Standardization Efforts**
3. Introduction to the Common REMS Platform

FDA and others are already using health data standards in REMS

Major efforts include:

1. Creating standards for how the REMS is described
2. Creating standards for how dispensers verify that safe use conditions are in place
3. Creating standards for how prescribers document safe use conditions

Standards for how the REMS is described

REMS SPL

Proposal was identified by stakeholders (in particular, the National Council for Prescription Drug Programs) leading up to our July 2013 public meeting

- SPL is well-equipped to capture REMS information
- SPL unites REMS information with other relevant product information
- Using SPL lets us leverage existing data standards process and infrastructure

In September 2015, FDA adopted REMS SPL as a PDUFA VI “Priority Project”

REMS SPL captures the "4 W's" of REMS

Data Element	Description	Examples
Stakeholder ("Who")	The party that must meet the REMS requirement	prescriber, dispenser, health care setting
Protocol ("When")	A particular "stage" in the treatment process around which REMS activities may occur	certification, prescribing, dispensing, administration
Requirement ("What")	A clinical or administrative activity that must be performed as part of the REMS	counseling a patient, completing an enrollment form, lab testing
Material reference ("With What")	Reference to approved REMS material with which the requirement is carried out	enrollment form, medication guide, educational pamphlet

REMS documents are transformed into REMS Summaries

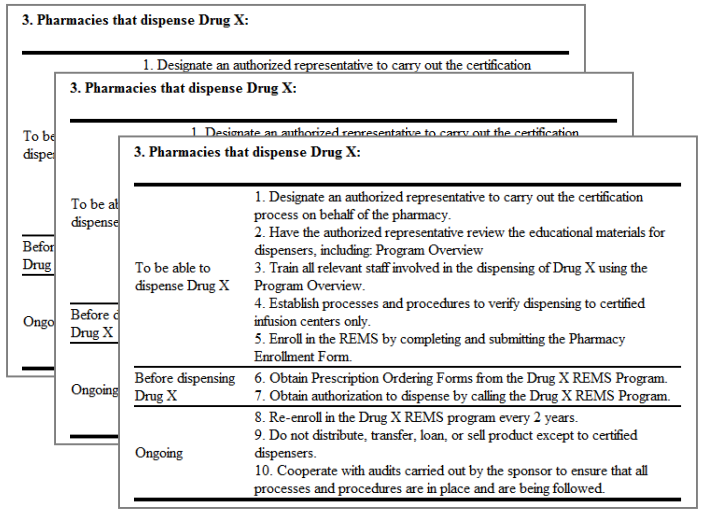
REMS Document Text

To become certified, each prescriber must activate registration, by completing the Prescriber Enrollment Form, via the iPLEDGE website or the automated phone system.

The healthcare provider completes the Healthcare Provider Enrollment Form.

To become certified, each prescriber must complete the Prescriber Enrollment Form

REMS Summaries

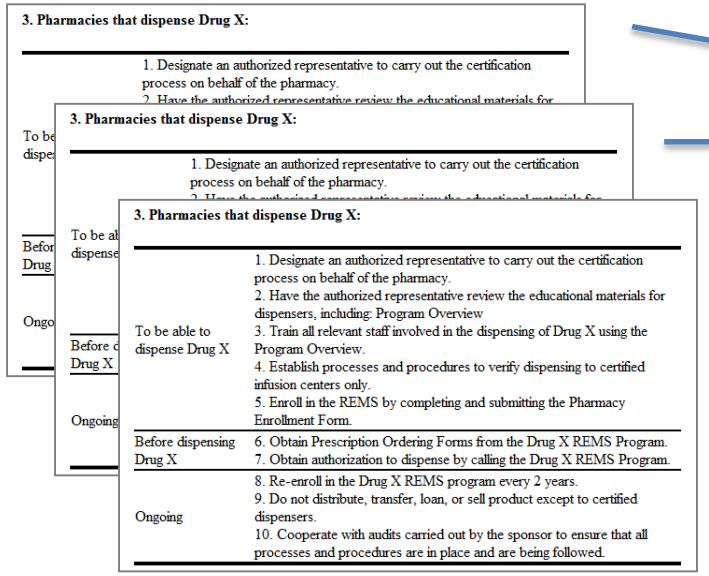


3. Pharmacies that dispense Drug X:

To be able to dispense Drug X	1. Designate an authorized representative to carry out the certification process on behalf of the pharmacy. 2. Have the authorized representative review the educational materials for dispensers, including: Program Overview 3. Train all relevant staff involved in the dispensing of Drug X using the Program Overview. 4. Establish processes and procedures to verify dispensing to certified infusion centers only. 5. Enroll in the REMS by completing and submitting the Pharmacy Enrollment Form.
Before dispensing Drug X	6. Obtain Prescription Ordering Forms from the Drug X REMS Program. 7. Obtain authorization to dispense by calling the Drug X REMS Program.
Ongoing	8. Re-enroll in the Drug X REMS program every 2 years. 9. Do not distribute, transfer, loan, or sell product except to certified dispensers. 10. Cooperate with audits carried out by the sponsor to ensure that all processes and procedures are in place and are being followed.

REMS Summaries are then transformed into standardized data elements

REMS Summaries



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Standardized Data Elements

Stakeholder	Prescribers
Protocol	To be able to prescribe
Requirement	Enroll in REMS

Example of codified REMS within SPL

```
<protocol>
    <code code="C0P03" codeSystem="2.16.840.1.113883.3.26.1.1"
    <component>
        <sequenceNumber value="1"/>
        <requirement>
            <code code="C0R002" displayName="Counsel patient"
                <originalText>
                    <reference value="#A005"/>
                </originalText>
            </code>
            <participation typeCode="PPRF">
                <stakeholder>
                    <code code="C0SH01" displayName="prescribe
                </stakeholder>
            </participation>
            <subject>
                <documentReference>
                    <id root="00000000-0000-0000-0000-00000000
                        <!-- Document reference links to docum
                    </id>
                </documentReference>
            </subject>
        </requirement>
    </component>
```

When:
- While prescribing (C0P03)

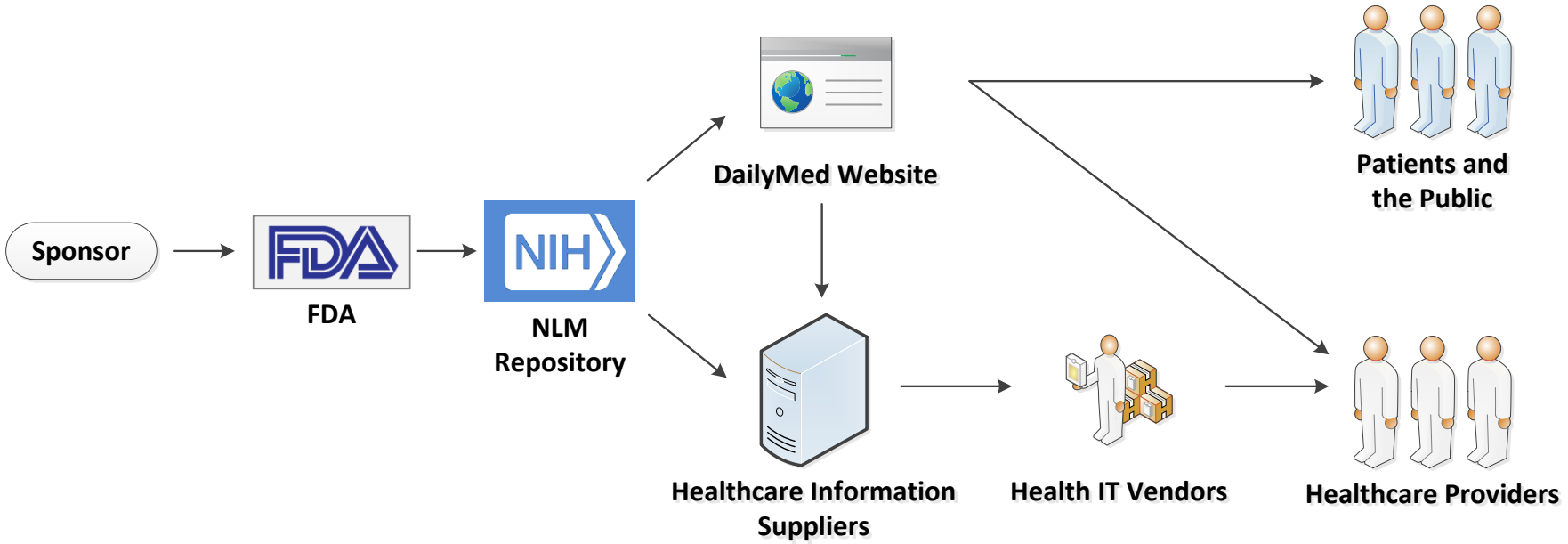
What:
- Counsel patient (C0R002)

Who:
- Prescriber (C0SH01)

Using What:
- documentReference

SPL information is shared across the healthcare system

SPL data is transmitted from the sponsor to patients, healthcare providers, and the public



SPL: Progress so Far

- FSeptember 2014: FDA established SPL and REMS as a "priority project" under PDUFA V
- FFebruary 2015: REMS-specific data elements were balloted with HL7
- FOctober 2015: FDA announced registration for REMS SPL pilot at public meeting
- FDecember 2015: Pilot kicked off with 9 sponsors
- FMay 2016: Pilot completed

Next steps

- Obtain feedback from stakeholders on…
  - Industry experience with pilot
  - Whether the information provided in REMS SPL adequately addresses end-user needs
- Educate and share lessons learned
- Prepare to receive regulatory submissions in SPL format
  - Finalize implementation guide based on feedback from pilot
  - Establish official controlled terminology for REMS programs
  - Ensure that REMS SPL will be available on DailyMed

Standards for Verifying Safe Use Conditions

- Pharmacist plays key role in REMS as the last checkpoint before patient receives prescription.
- In many REMS with ETASU, pharmacists are asked to go to a website or call center to verify that certain "safe use conditions" are in place prior to dispensing, for example:
  - Prescriber is enrolled and trained
  - Patient monitoring has been completed
  - Patient has been counseled on the drug's risks
- Pharmacists have been concerned that existing processes are cumbersome and time-consuming.

Improving the Process

- FDA reached out to pharmacy groups and asked them how to better integrate REMS into their workflow.
- Overwhelming response: use established data standards for verification of safe use conditions.
  - Use the NCPDP standard already used by most pharmacy systems
  - This standard already includes many data elements needed by REMS
- NCPDP developed an implementation guide in 2010 to help sponsors use the Telecommunications Standard, NCPDP's standard for pharmacy claims, to support REMS

The New REMS Pharmacy Workflow

1. The pharmacist enters claim information into their computer as normal.
2. The pharmacy system sends this claim to a “switch” who, instead of sending the claim to the insurer, first sends relevant REMS information to a “REMS Administrator
3. If safe use conditions are in place, the claim moves on to the insurer. Otherwise, the pharmacist receives an error message

REMS in Pharmacy Systems: Progress to Date

- In 2011, FDA approved the first REMS that utilizes this "switch system" to verify safe use conditions.
- Additional REMS are continuing to transition to the new system
- Stakeholders have provided a lot of positive feedback on the REMS that utilize this system (although not all have been able to adopt it.)

REMS and ePrescribing

NCPDP is now working integrate REMS checks into ePrescribing and EHRs to help document safe use conditions.

- The system leverages NCPDP's SCRIPT standard, used for ePrescribing and electronic prior authorization.
- The system allows REMS administrators to present prescribers with a "question set" similar to those used in prior authorization.

Prior Authorization Question for Transmucosal Immediate Release Fentanyl (TIRF):

4	Is the drug being prescribed for the management of breakthrough pain in a CANCER patient who is currently receiving around-the-clock opioid therapy for underlying CANCER pain?	Yes	No

TIRF REMS Patient-Prescriber Agreement Form:

1. I understand that TIRF medicines are indicated only for the management of breakthrough pain in patients with cancer, who are already receiving, and who are tolerant to, around the clock opioid therapy for their underlying persistent pain.

Contents

1. Background on Health Data Standards in REMS

2. Existing Standardization Efforts

3. **Introduction to the Common REMS Platform**

Current Challenges

There has been a great deal of progress in the development and adoption of these standards, but challenges remain…

- Many REMS activities and healthcare settings are not addressed by the existing standards
- Most REMS have not yet adopted the standards that have been created.

What is the Common REMS Platform?

The platform is really just two things:

1. A catalog, maintained by FDA, of electronic data standards by which REMS can operate and communicate

2. A process (both internal and external) for creating or updating standards and having them added to this catalog

REMS Platform Process

I. Standards Development

- Identify standardization needs and develop use case
- Work with SDO to develop standard and pilot it

II. Standards Acceptance

- Review developed standards
- Add standards to Platform Standards Catalog
- Develop instructions for integrating standards into REMS

III. Standards Adoption

- Identify REMS to which the standards apply
- Encourage/Require REMS to adopt platform standards

I. Standards Development
Identify and Develop Use Case

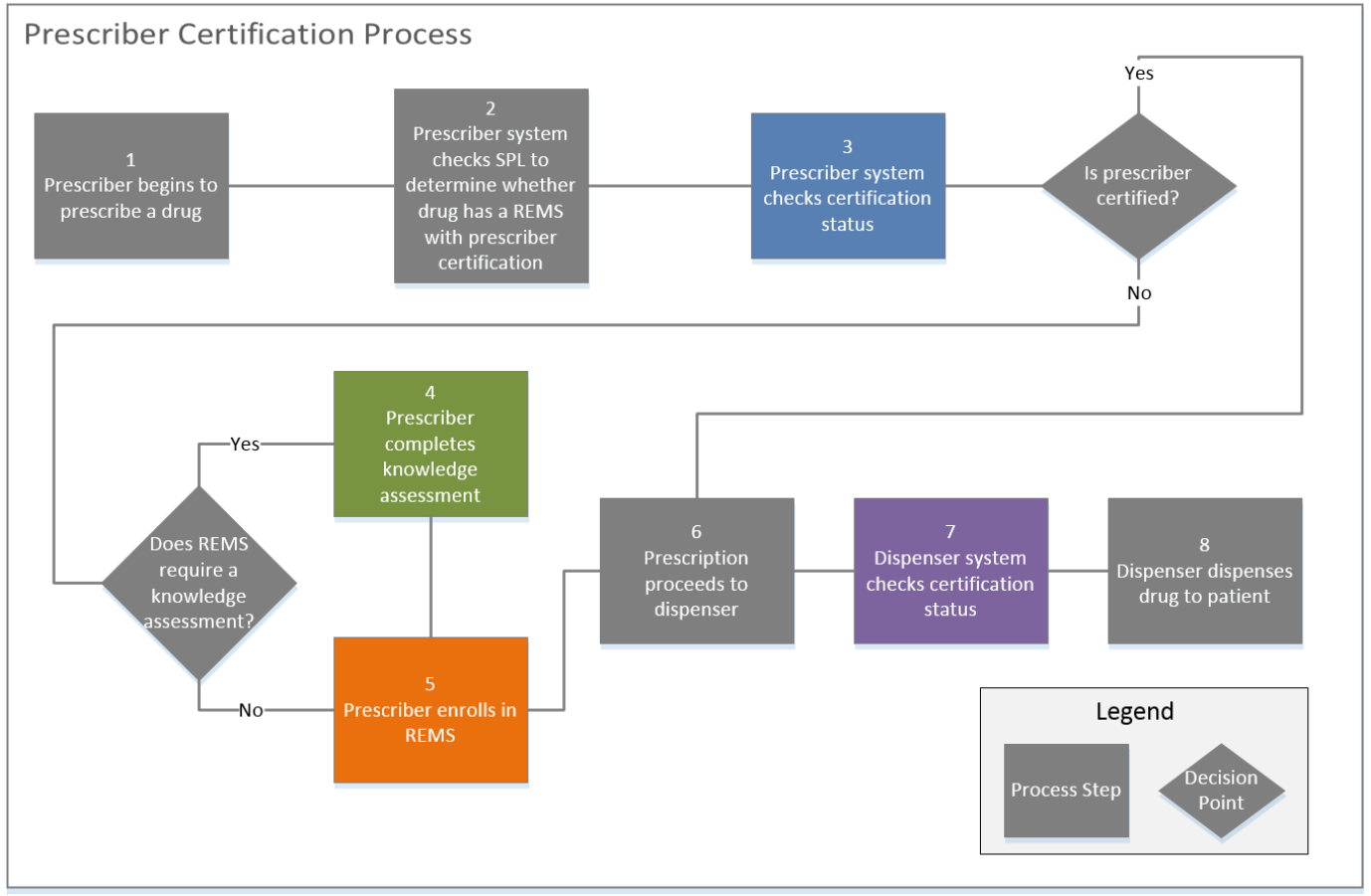
Use Case: A description of the REMS activity to be standardized, how stakeholders and systems interact to perform the activity, and what the standard needs to accomplish.

Possible REMS use cases include:

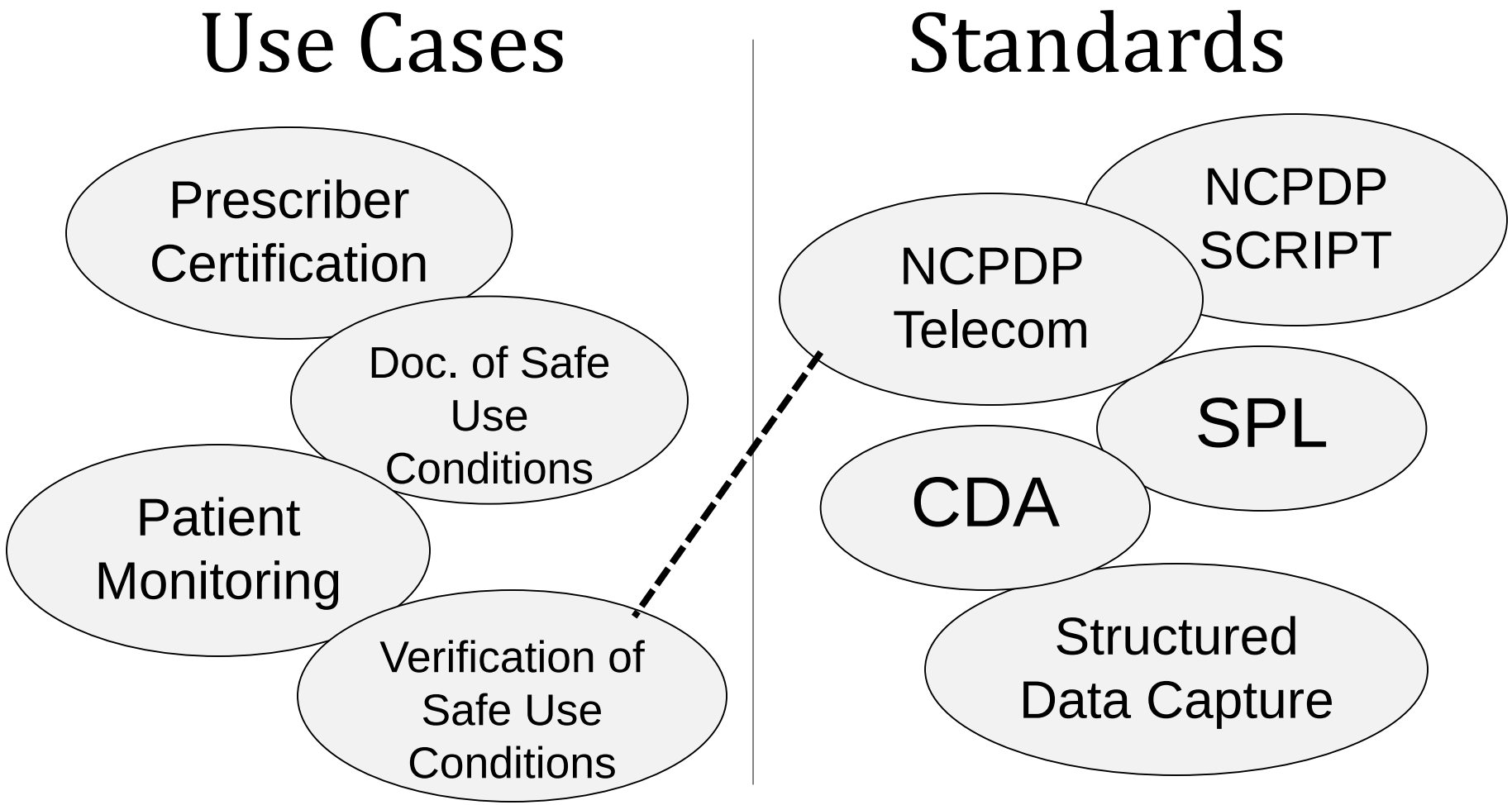
- Healthcare Provider Enrollment and Certification
- Patient Enrollment and Agreement
- Documentation of Safe Use Conditions by the Prescriber
- Verification of Safe Use Conditions by the Dispenser

I. Standards Development
Identify and Develop Use Case

Sample Use Case Diagram



I. Standards Development
Develop Standard and Pilot It



I. Standards Development
Develop Standard and Pilot It

Implementation guides describe precisely how standards would be used to carry out REMS activities

Excerpt from NCPDP's Draft REMS ePrescribing Implementation Guide:

1.1.1.1 REMSResponse Transaction

The REMSResponse provides the mechanism for the REMS Administrator to relay approval or denial of the medication, patient, prescriber, and/or pharmacy for the designated REMS program, or if more information is needed.

Response is used to denote <Approved> or <Denied> by the REMS Administrator.

For information on <ReturnReceipt> functionality, see section "*Verify Transaction*" in the NCPDP ***XML Standard***. For information on Status, Error and GetMessage transactions, see this same document.

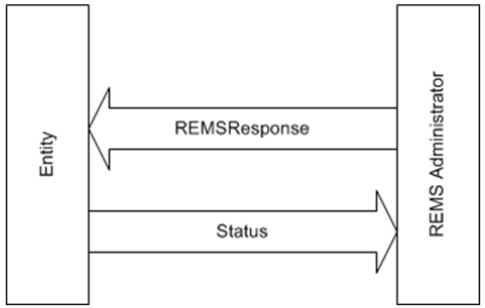


Figure 43x. REMSRequest Flow

II. Standards Acceptance
Add standards to Platform Standards Catalog

The standards development process would culminate in a "version 1.0" catalog of "REMS Platform Standards"

FDA Data Standards Catalog v4.3 (05-27-2015) - Supported and Required Standards

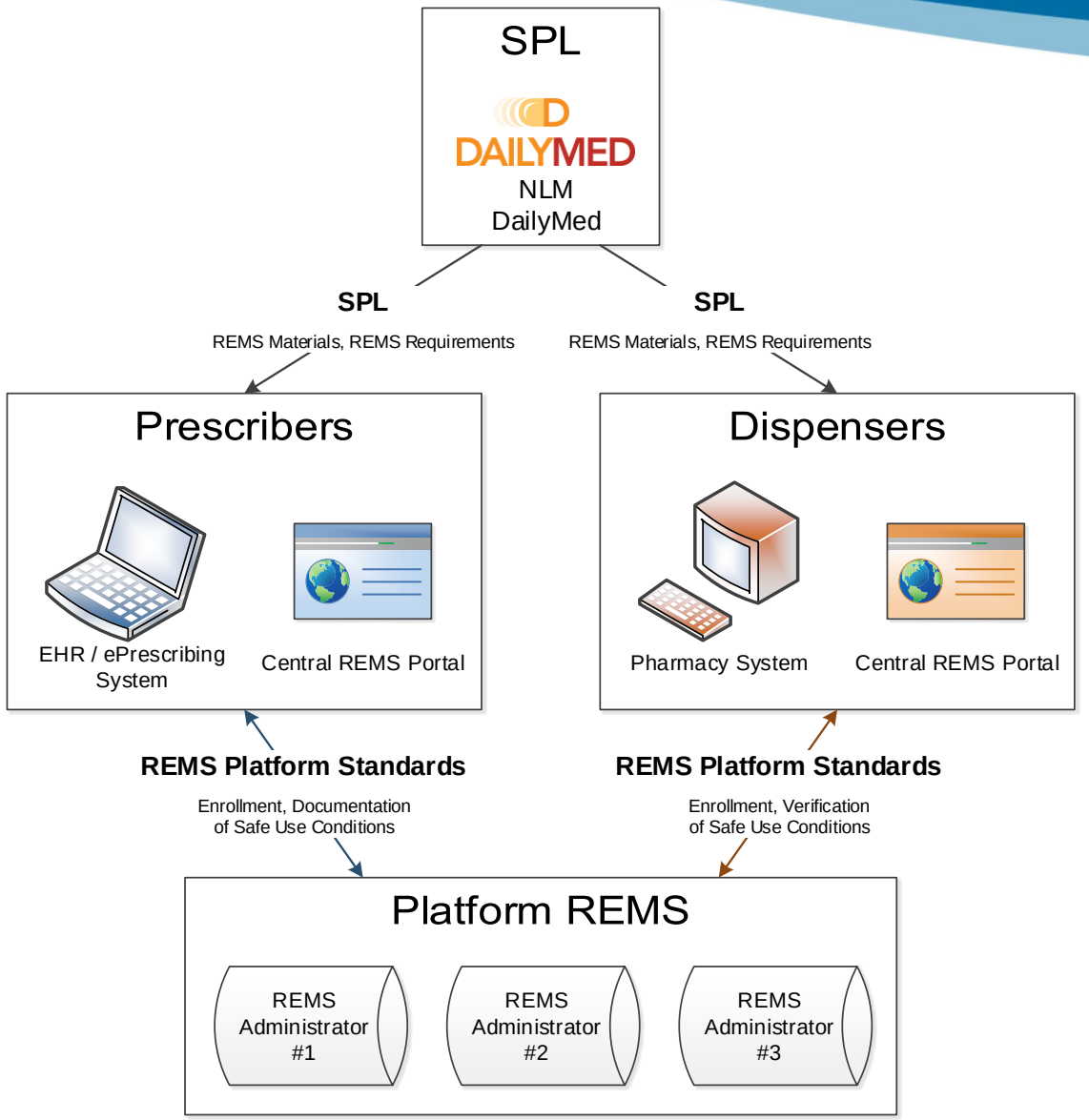
This table contains a listing of the data exchange, file formats and terminology standards supported at FDA. These standards have gone through all the steps necessary to make this part of the regulatory review process, including posting of regulatory guidance documents and associated implementation guidelines and technical specifications. The submission of standardized data using any standard not listed, or to an FDA Center not listed, should be discussed with the Agency in advance. This catalog is incorporated by reference in the guidance to industry, *Providing Regulatory Submissions in Electronic format-Standardized Study Data (http://www.fda.gov/downloads/Drugs/Guidances/UCM292334.pdf).* A separate catalog will be published in the future that will contain a listing of standards that are in the development, testing, adoption or research & development (R&D) phases.

Use	Data Exchange Standard	Exchange Format	Standards Development Organization (SDO)	Supported Version	Implementation Guide Version	FDA Center(s)	Date Support Begins (MM/DD/YYYY)	Date Support Ends (MM/DD/YYYY)	Date Requirement Begins (MM/DD/YYYY)	Date Requirement Ends	Regulatory Reference and Information Sources
Regulatory Applications (IND, NDA, ANDA, BLA, master files)	Electronic Common Technical Document (eCTD)	Extensible Markup Language (XML)	International Conference on Harmonisation (ICH)	3.2.2	M2 eCTD: Electronic Common Technical Document Specifications	CDER, CBER	06/01/2008		05/05/2017 [5] 05/05/2018 [6]		Electronic Submissions-Electronic Common Technical Document (eCTD)
Product Labeling Submissions	Structured Product Labeling (SPL)	XML	Health Level 7 (HL7)	Release 5		CDER, CBER	Ongoing		04/01/2005 [3] 12/11/2003 [4]		StructuredProductLabeling (SPL) Implementation Guide with Validation Procedures
Postmarketing Safety Reporting - Adverse Events for Medical Devices	Individual Case Safety Report (ICSR)	XML	HL7	Release 1	N/A	CDRH	Ongoing				Electronic Medical Device Reporting (eMDR) - Device Regulation and Guidance

Over time, FDA, in consultation with stakeholders, could make changes to this set of standards.

III. Standards Adoption

Potential REMS Platform Model



Benefits of a Common REMS Platform

- It reduces the amount of work stakeholders must do to integrate REMS into their processes.
- It has the potential to improve REMS processes
- It simplifies REMS development and reduces the amount of uncertainty in the development process
- Helps ensure that REMS with similar risks are similar
- It allows for the creation of centralized REMS tools and resources

Key questions moving forward

- How can a common REMS platform help foster innovation and improve care?
- How can we effectively work together to advance the REMS platform?
- What does a successful collaboration look like?

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June 7, 2016

Use of NCPDP Standards in Risk Evaluation and Mitigation Strategies (REMS)

Michele V. Davidson, R. Ph.

June 7, 2016

NCPDP™

Bio and Disclosure

Michele V. Davidson, R.Ph. is the Manager of Pharmacy Technical Standards, Policy & Development with Walgreens. She has been an active member of NCPDP for over 15 years and served as the Chair of the Board of Trustees. She leads the WG11 REMS and ePrescribing Task Group and served as co-chair for Work Group 11 ePrescribing and Related Transaction for eight years. She was the 2014 recipient of the NCPDP TIME (The Individual Member Excellence) Award.

She has no conflicts of interest to disclose.

NCPDP™

Agenda

- Who is NCPDP
- NCPDP Transactions
- Minimizing Burden of REMS through standardization
- Telecommunication REMS Standard
- ePrescribing REMS Transaction

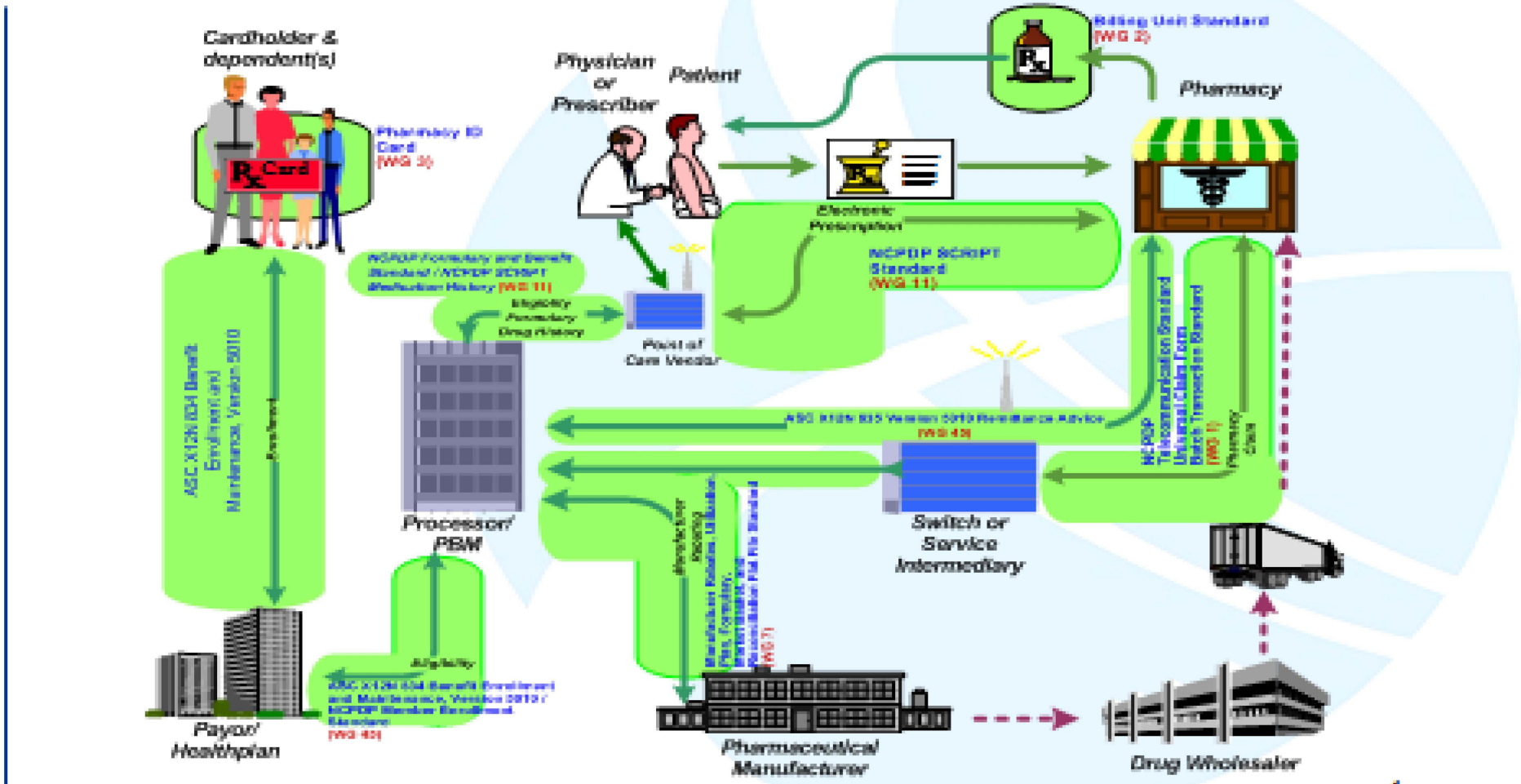
NCPDP™

NCPDP

Multi-stakeholder, Problem-solving Forum for Healthcare

- ANSI-accredited Standards Development Organization
- Standards for Electronic Exchange of Information
- Many of our standards are named in federal legislation, including HIPAA, MMA, HITECH and Meaningful Use (MU)
- Best Practices for Patient Safety
- Advisor to Policymakers
- Founder & Chair of Standards Charter Organization (SCO)

NCPDP™


Cardholder & dependent(s)
Physician or Prescriber
Patient
Billing Unit Standard (WG 2)
Pharmacy
Pharmacy ID Card (WG 3)
Electronic Prescription
NCPDP SCRIPT Standard (WG 11)
Point of Care Vendor
Processor/ PBM
Switch or Service Intermediary
Payor/ Healthplan
Pharmaceutical Manufacturer
Drug Wholesaler

Minimizing the Burden of REMS through Standardization

- Currently implemented standardized solution for pharmacies using NCPDP Telecommunication Standard (e.g. TIRF REMS)
- Currently published solution for prescribers using the **NCPDP SCRIPT Standard** for electronic prescribing**.**

NCPDP™

REMS

Telecommunication Standard
Pharmacy Claims billing

NCPDP™

National Council for Prescription Drug Programs
NCPDP

Prescriber & Dispenser Workflow

Maximize:

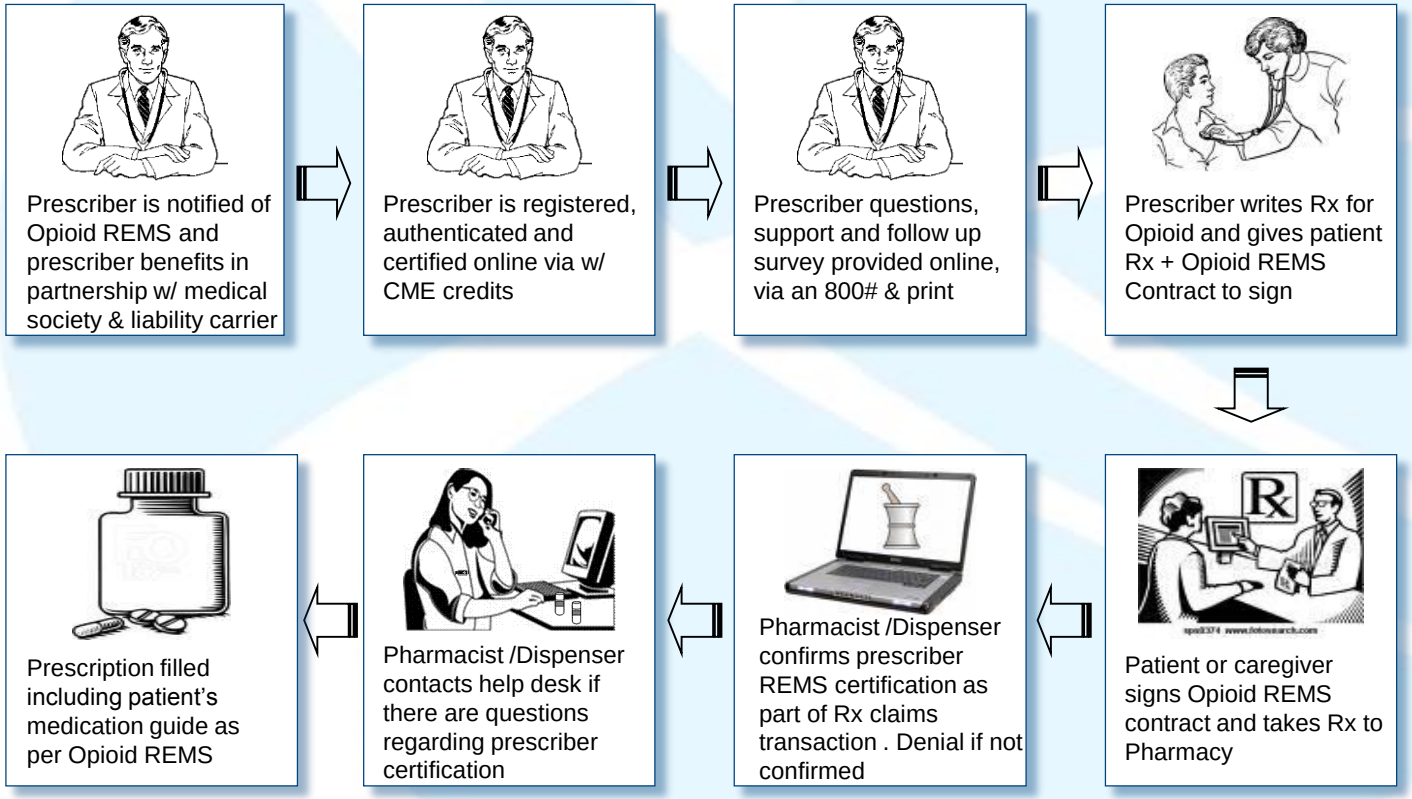
- Patient access
- Prescriber participation & benefits
- Support and endorsement of key partners
- Efficiency
- Satisfaction of FDA

Minimize:

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

REMS Functional Workflow

Prescriber, Patient, Pharmacist



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Key Challenges / Solutions

Key Challenges	Solution
Develop a REMS program acceptable to the FDA, manufacturers and providers	▪ Use existing technologies and relationships to fulfill key FDA requirements while minimizing costs and complexity for manufacturers and providers
Successfully engage and motivate pharmacies & pharmacists/dispensers to maximize participation	▪ Maximize pharmacy benefits including CME ▪ Minimize workflow disruptions by leveraging existing standards ▪ Supports reimbursement for professional activities
Deliver a Registration Interface solution that ensures compliance	▪ Integrated with billing process (i.e. Hard Stop) ▪ Point of dispense

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Key Challenges / Solutions

Key Challenges	Solution
Successfully engage and motivate prescribers to maximize participation and ensure patient access	▪ Coordinated prescriber outreach in partnership with: – Manufacturers, – Medical societies, and – Liability carriers ▪ Maximize prescriber benefits including: – CME and – Liability credits ▪ Optimize paper and electronic services for current national EHR incentives and adoption (HITECH Act)

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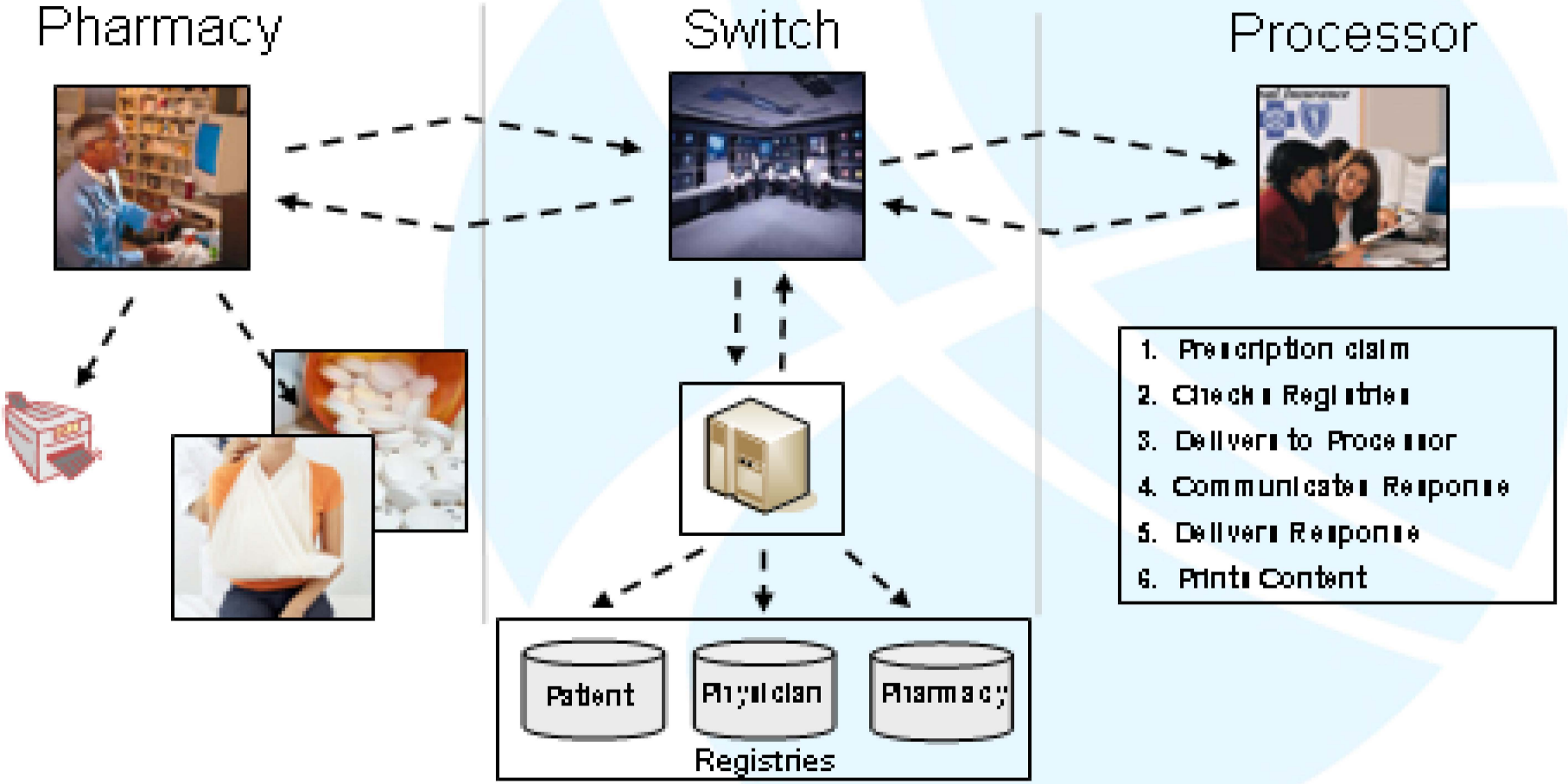
Transaction – Piggy-Back on Claim



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REMS Transaction is used Today

- TIRF
- Clozapine
- Qsymia
- Addyl
- iPLEDGE (Walgreens initiated)

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NCPDP & REMS Fields

Data:	Field:	Status:
Pharmacy	Service Provider ID	Existing
Product	Product / Service ID	Existing
Prescriber	Prescriber ID	Existing
Pharmacist	Provider ID	Existing
Patient	Patient ID	Existing
Patient ZIP	Patient ZIP/Postal Zone	Existing

REMS

SCRIPT Standard
E-Prescribing Standard

NCPDP™

Current Challenges for Prescribers

- 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. This results in:
  - Patients often discover they are unable to receive a drug when they appear at the pharmacy
  - Issues that could have been resolved in the prescribers office are left to the pharmacist.

Transaction Overview

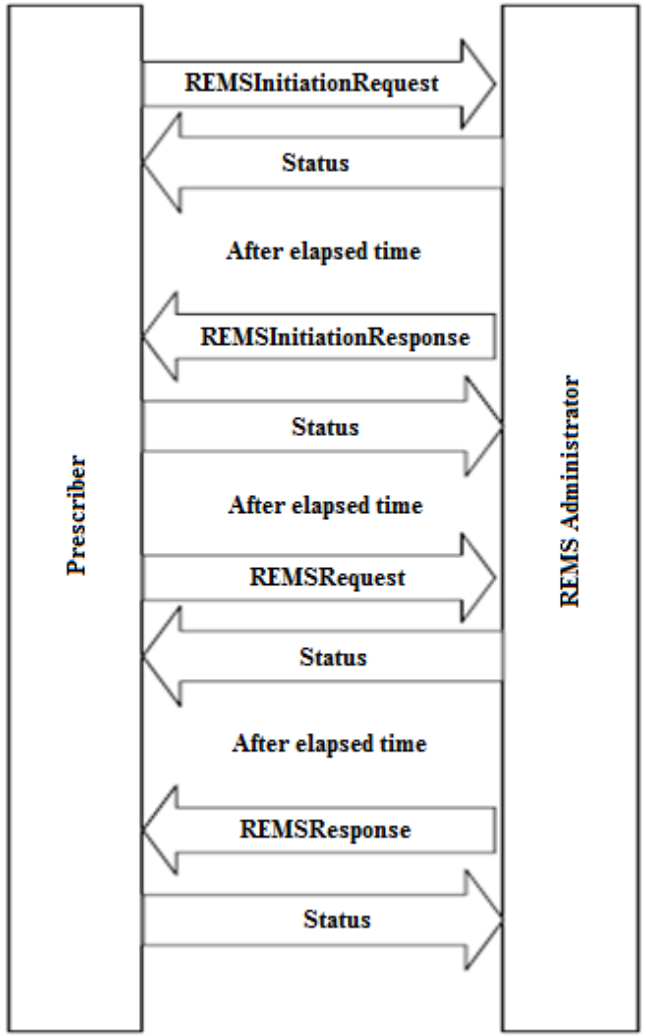
- Triggered in EHR by Structure Product Labeling (SPL)
  - Sends REMS Initiation Request to REMS Administrator
  - REMS Administrator approves or initiates Q & A set (ePA model)
- Upon completion, NewRx sent to pharmacy
  - May contain REMS Authorization #

How Will Electronic Health Records (EHR) Know REMS Is Required?

- SPL will include REMS fields
- EHR configured to read new REMS fields
- Key items found are **REMS Required** flag and the **REMS application holder**
  - May need some type of routing information

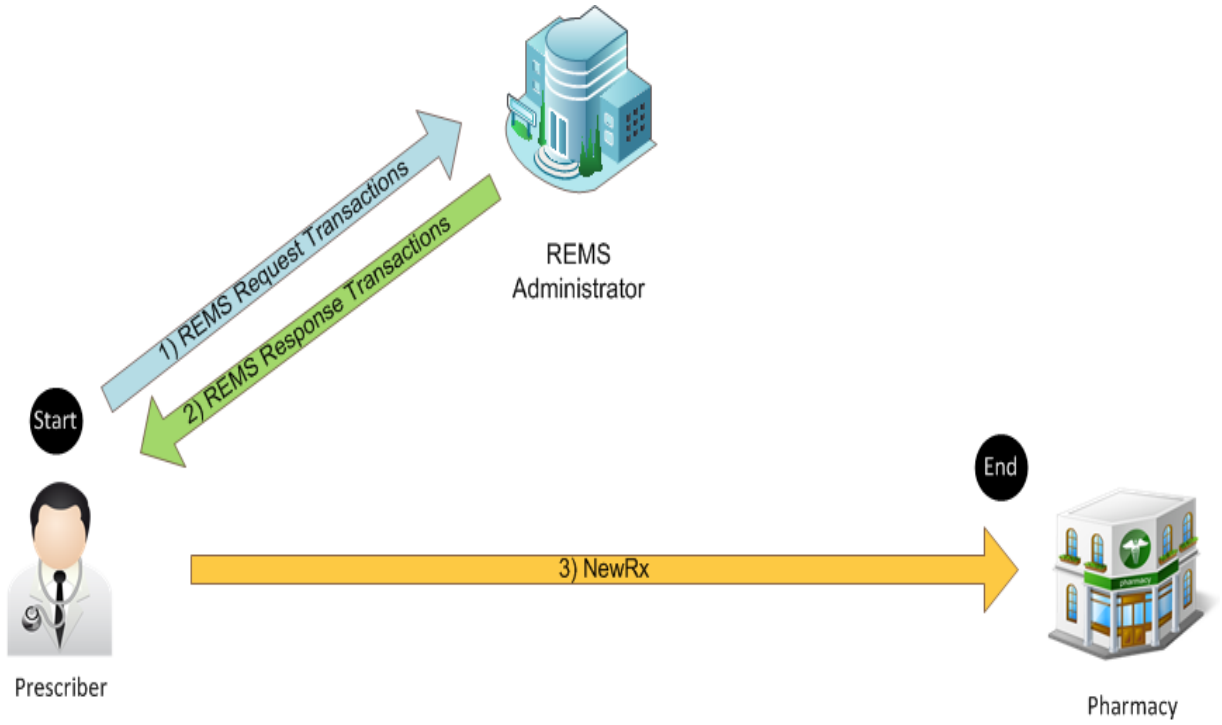
ETASU REMS Example

- REMS Administrator requires basic prescription and process questions to be answered
- EHR sends REMSInitiationRequest with prescriber, product and patient details
- REMS Administrator provides relevant questions in REMSInitiationResponse
- EHR provides details in REMSRequest
- REMS Administrator approves the prescribing of the medication for this patient in REMSResponse
- EHR sends NewRx to pharmacy with new REMS fields



REMS Transaction

REMS transactions are exchanged as are other SCRIPT Standard transactions, in a real-time request and response mode



Thank you!

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Building a Common Risk Evaluation and Mitigation Strategies (REMS) Platform

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