REMS Standardization & Healthcare Integration Initiatives

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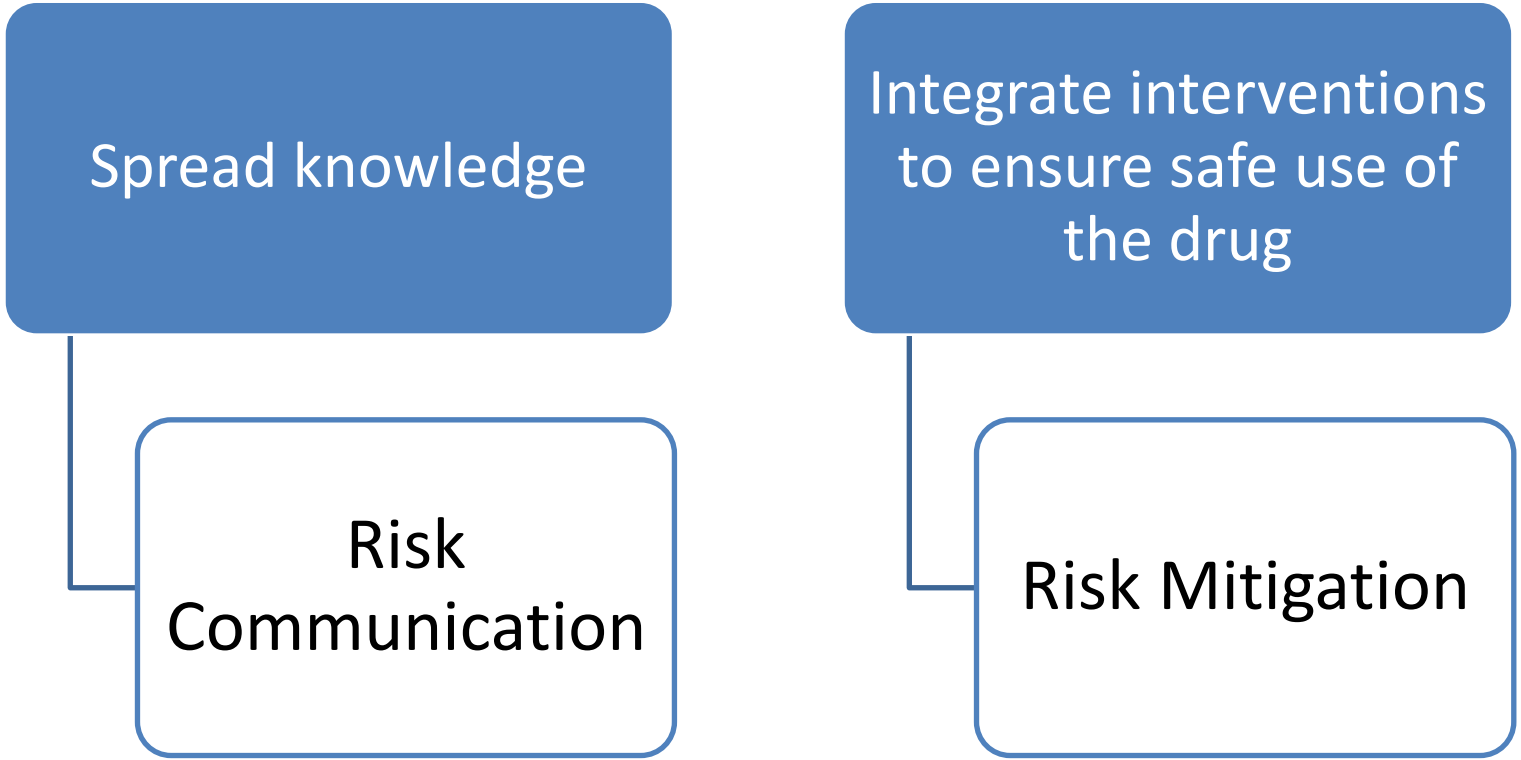
Learning Objectives

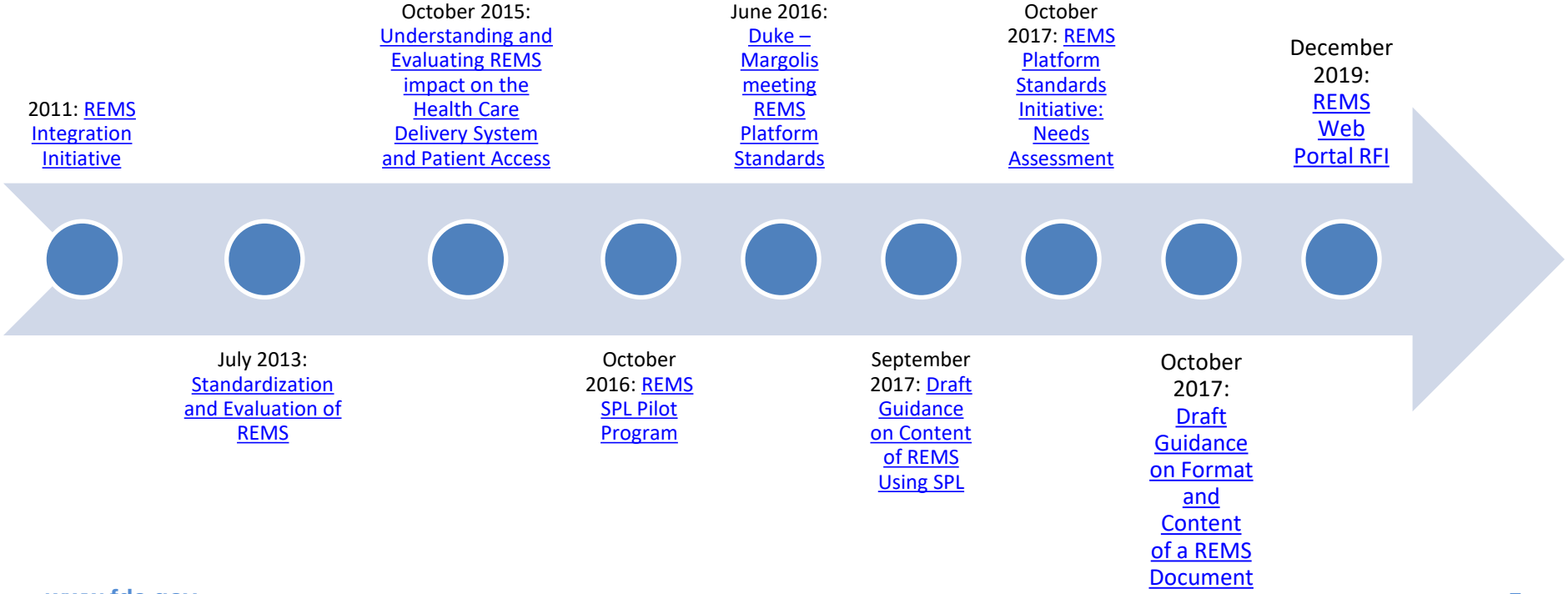
- Describe ongoing REMS standardization efforts
- Understand the importance of REMS standardization and integration
- Discuss opportunities and challenges in integrating REMS in to the healthcare system

A Complex System

REMS Programs



Efforts to Standardize & Integrate REMS

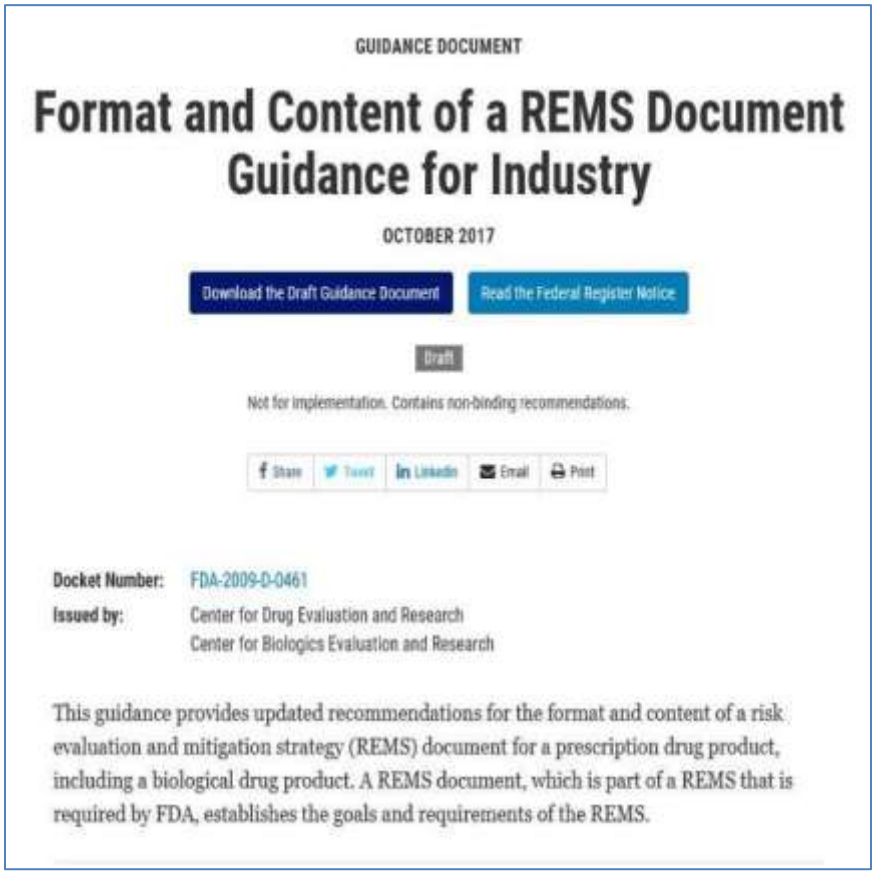


Risk Communication	REMS document
	Structured Product Labeling (SPL)
	REMS@FDA

REMS Standardization

REMS Document

- Communicates REMS requirements
- Standardizes the format
- Standardizes the way the requirements are being conveyed to stakeholders



GUIDANCE DOCUMENT

Format and Content of a REMS Document Guidance for Industry

OCTOBER 2017

Download the Draft Guidance Document | Read the Federal Register Notice

Draft

Not for implementation. Contains non-binding recommendations.

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Docket Number: FDA-2009-D-0461

Issued by: Center for Drug Evaluation and Research
Center for Biologics Evaluation and Research

This guidance provides updated recommendations for the format and content of a risk evaluation and mitigation strategy (REMS) document for a prescription drug product, including a biological drug product. A REMS document, which is part of a REMS that is required by FDA, establishes the goals and requirements of the REMS.

Standardized Format

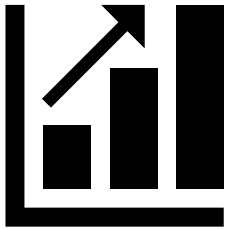
FarmFa must ensure that health care providers, patients, pharmacies, and wholesalers/distributors comply with the following requirements:

Who

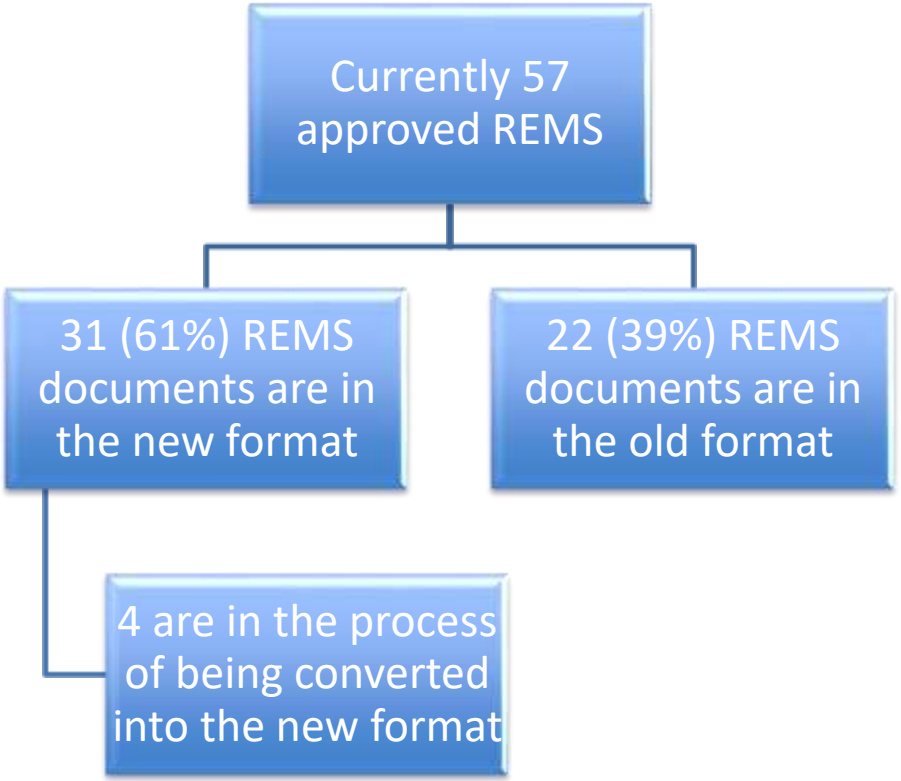
1. Health care providers who prescribe Welipax must:

When	**What**	**With What**
To become certified to prescribe	1. Review the drug's Prescribing Information	
	2. Review the Prescriber Education Program.	
	3. Enroll in the REMS by completing the Prescriber Enrollment Form and submitting it to the REMS Program.	
Before treatment initiation (first dose)	4. Counsel the patient that holiday stress occurs with patients treated with Welipax, to be aware of symptoms and steps to take if symptoms occur.	
	5. Provide the patient with the Patient Wallet Card	
	6. Enroll the patient by completing and submitting the Patient-Prescriber Agreement Form to the REMS Program. Retain a copy in the patient's record.	
At all times	7. Inform FarmFa if a patient is no longer under your care or has discontinued treatment	

REMS Documents in New Format



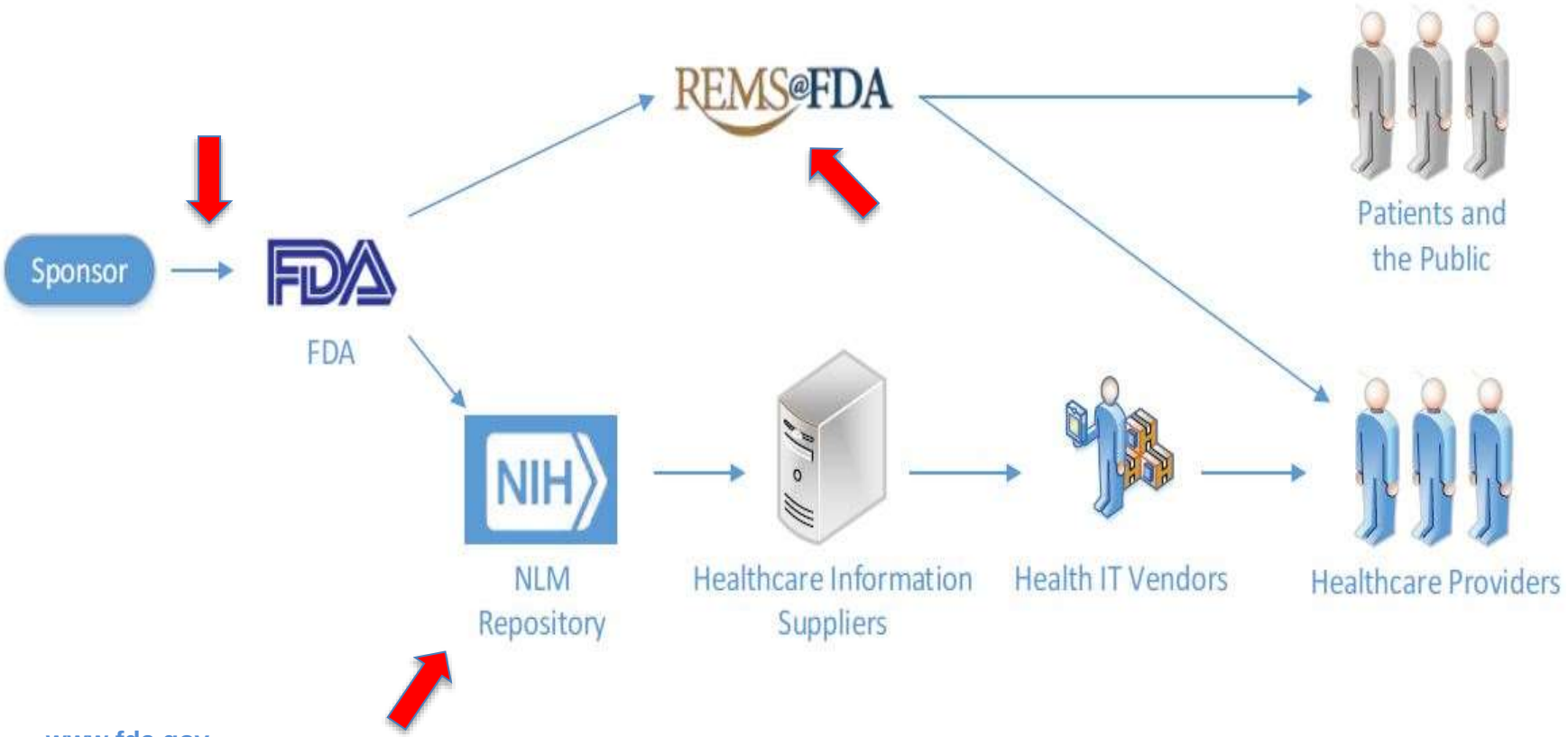
Over the past 2 years more than 50% of REMS are in the new format



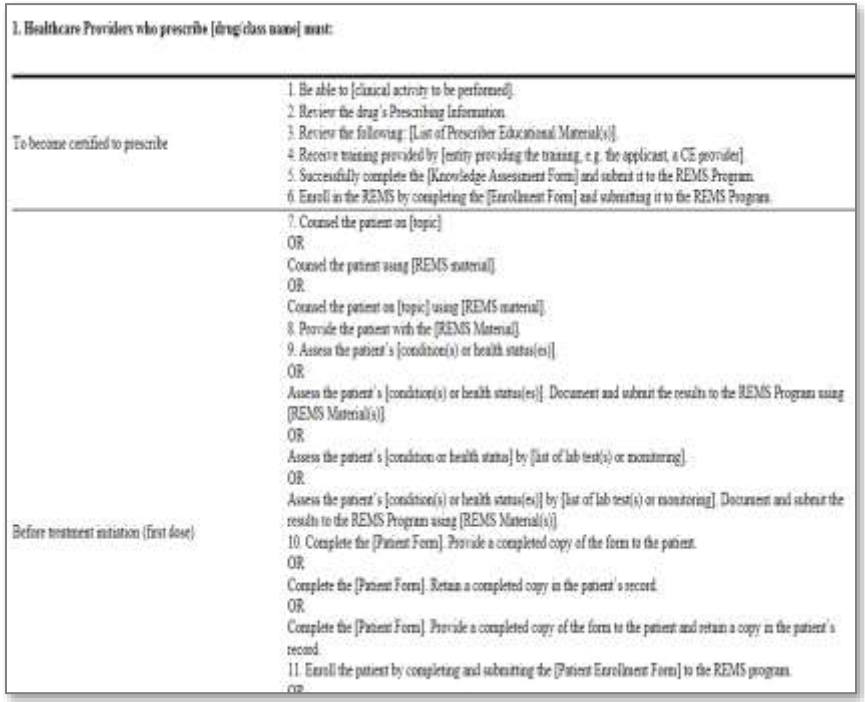
What is SPL?

- SPL (“Structured Product Labeling”) is a data standard for capturing information about drug products
- SPL is developed and maintained by a Standards Development Organization called Health Level Seven International (HL7)
- SPL enables the uptake of drug product information by drug information and health IT vendors

REMS & Structured Product Labeling



REMS SPL starts with the official "REMS Document"



1. Healthcare Providers who prescribe [drug/class name] must:	
To become certified to prescribe	1. Be able to [clinical activity to be performed]. 2. Review the drug's Prescribing Information. 3. Review the following: [List of Prescriber Educational Material(s)]. 4. Receive training provided by [entity providing the training, e.g. the applicant, a CE provider]. 5. Successfully complete the [Knowledge Assessment Form] and submit it to the REMS Program. 6. Enroll in the REMS by completing the [Enrollment Form] and submitting it to the REMS Program.
Before treatment initiation (first dose)	7. Counsel the patient on [topic]. OR Counsel the patient using [REMS material]. OR Counsel the patient on [topic] using [REMS material]. 8. Provide the patient with the [REMS Material]. 9. Assess the patient's [condition(s) or health status(es)]. OR Assess the patient's [condition(s) or health status(es)]. Document and submit the results to the REMS Program using [REMS Material(s)]. OR Assess the patient's [condition or health status] by [list of lab test(s) or monitoring]. OR Assess the patient's [condition(s) or health status(es)] by [list of lab test(s) or monitoring]. Document and submit the results to the REMS Program using [REMS Material(s)]. 10. Complete the [Patient Form]. Provide a completed copy of the form to the patient. OR Complete the [Patient Form]. Retain a completed copy in the patient's record. OR Complete the [Patient Form]. Provide a completed copy of the form to the patient and retain a copy in the patient's record. 11. Enroll the patient by completing and submitting the [Patient Enrollment Form] to the REMS program. OR

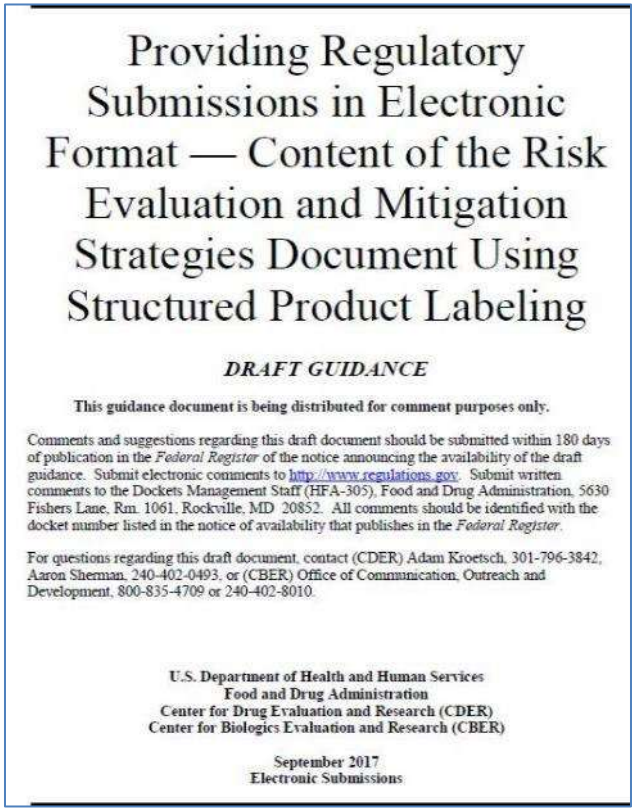
REMS SPL follows the format of the new REMS document template

What happens if my REMS is not in the new format?

- **You will need to create "REMS summary" tables**

REMS SPL Guidance

- This draft guidance and the "SPL implementation guide" describe the requirements for the electronic submission of the content of a REMS
- FDA is now finalizing the draft guidance
- Electronic submission requirements take effect 2 years from the publishing of a final guidance



Providing Regulatory Submissions in Electronic Format — Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 180 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Adam Kroetsch, 301-796-3842, Aaron Sherman, 240-402-0493, or (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

September 2017
Electronic Submissions

REMS in SPL Format

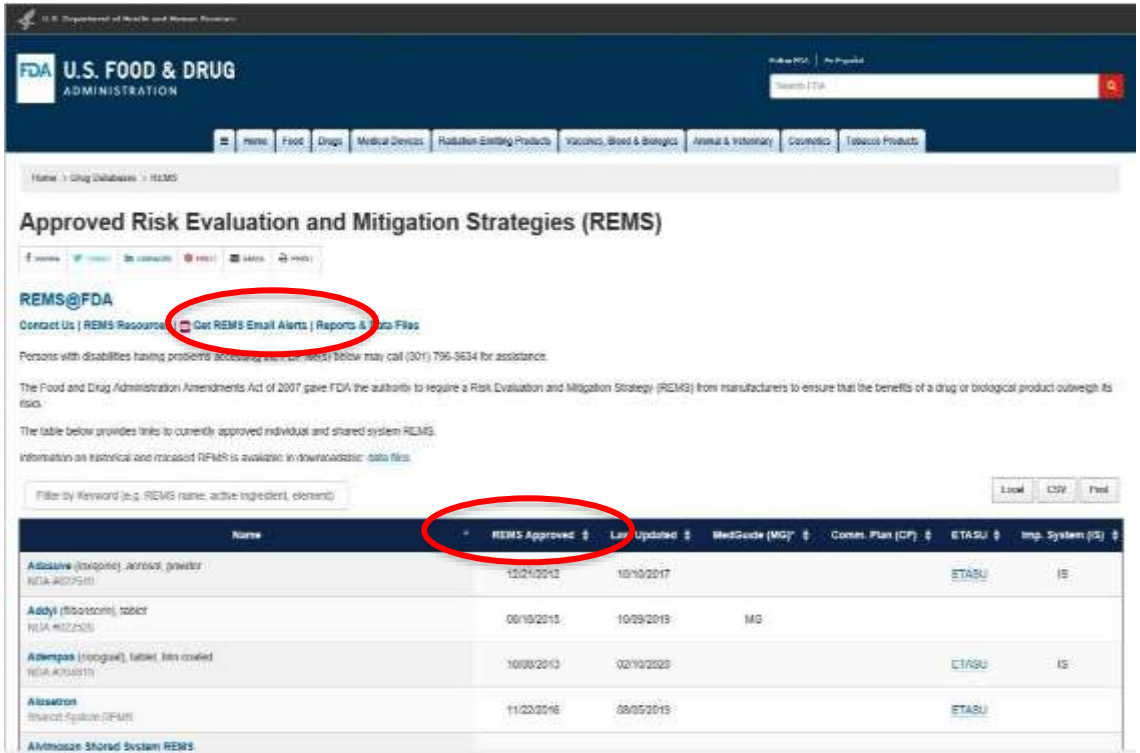
Of the 57 currently approved REMS

Less than 1% submitted in SPL

REMS@FDA

New website launched in 2015 (updated 2017) to provide a standardized, user-friendly, and up-to-date repository of REMS information

Improve communication about REMS and meet needs of various users



Challenge Question #1

To submit your REMS in SPL to the FDA, it is necessary to:

A. Have your REMS document in the new format

B. Create a REMS "summary" if your REMS document is in the old format

C. The format of your REMS document does not matter

D. A & B

Challenge Question #2

Sponsors will be <u>required</u> to submit their REMS document in SPL within:

A. 1 year from publication of the final guidance

B. 2 years from publication of the final guidance

C. It is already in effect

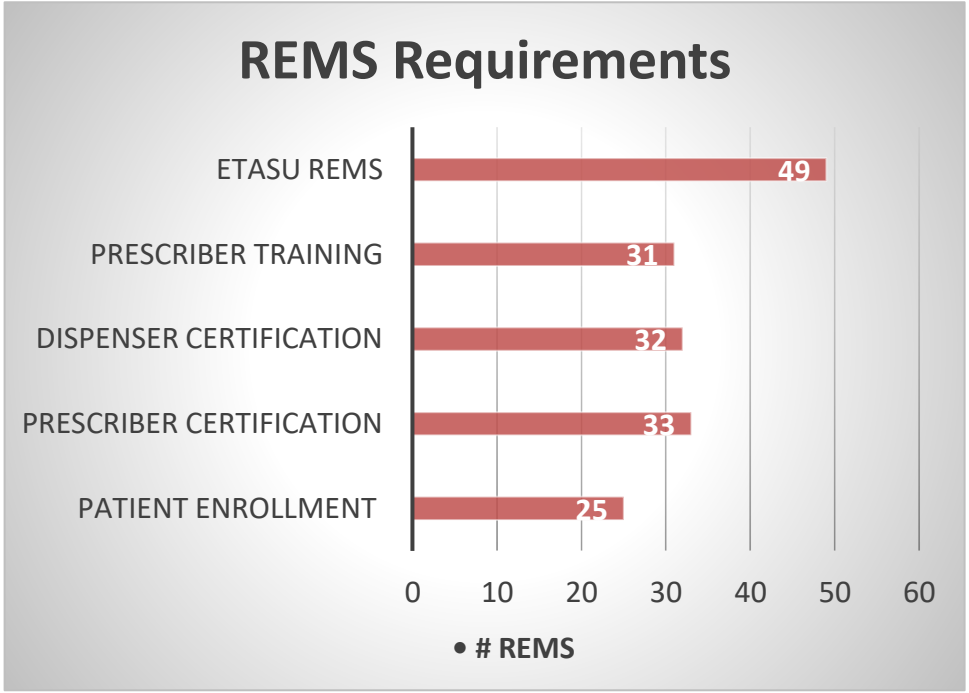
D. Never

Risk Mitigation Interventions	**Health IT data standards**
	NCPDP Standards
	REMS Web Portal Initiative

REMS Integration: Healthcare Systems

REMS requirements for stakeholders

- REMS with ETASU often requires:
  - Prescribers and pharmacist to be certified and trained
  - Patients be counseled and monitored
  - Certain safe-use conditions to be verified or documented before drug is dispensed



Source: REMS@FDA
Accessed April 2020

Integration into Workflow is Key

Considerations for REMS Integration

- Should be part of the clinical workflow
- Should be compatible with existing health Information technology (HIT)
- Should be flexible to adapt to changes in the healthcare system and new technologies
- Should allow for equal access

Health Data Standards

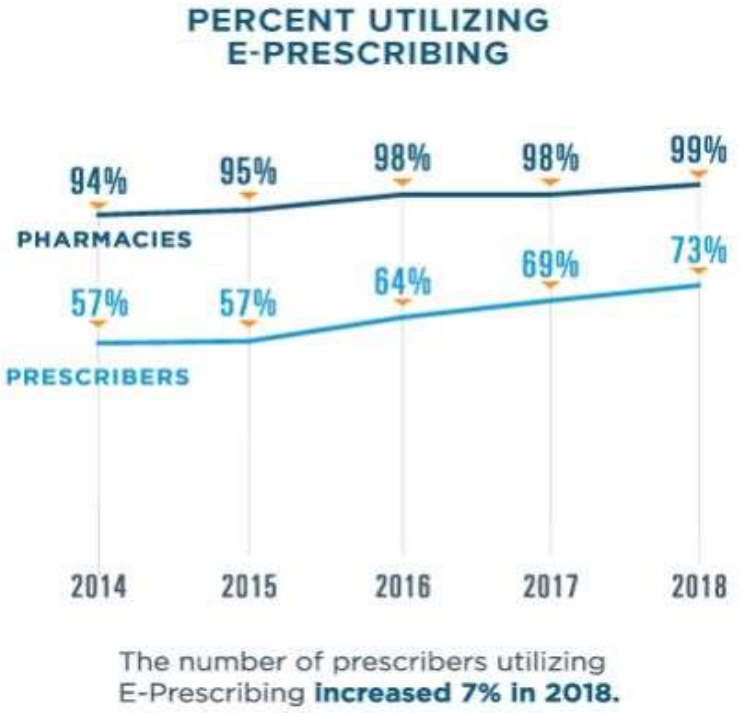
- Are a common way of (electronically) communicating health information
- Allow healthcare providers to work together in a large, complex, and increasingly electronic healthcare system
- Have a couple of distinctive features:
  - Not developed by FDA or government, but rather by Standards Development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

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

Leveraging Health Data Standards

First REMS was approved in 2008 when less than 10% of prescribers were e-prescribing

Most REMS have not leveraged health data standards

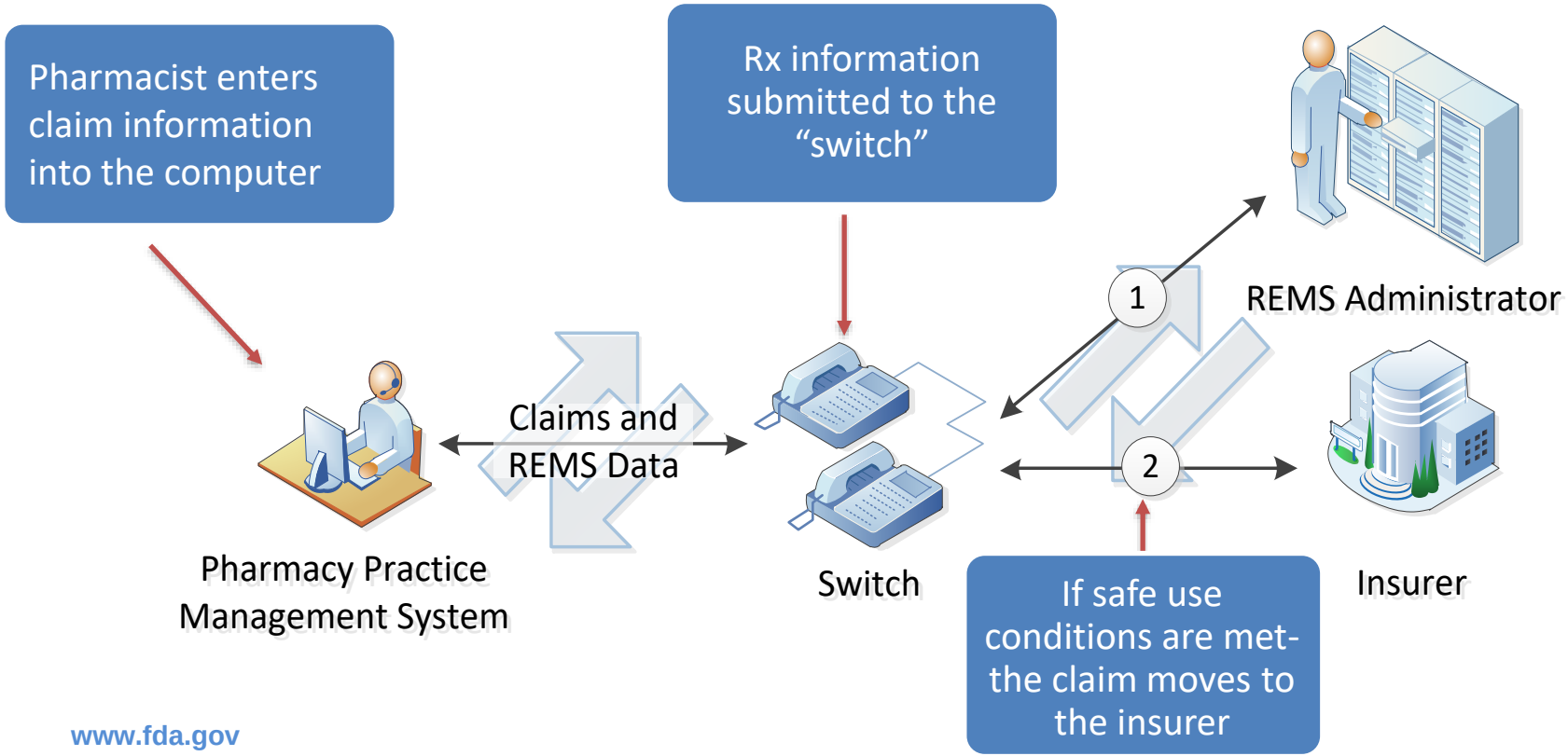


Source: 2018 Surescripts National Progress Report. Retrieved from https://surescripts.com/news-center/national-progress-report-2018/

NCPDP Telecommunication Standard

- NCPDP Telecommunication Standard (“Switch System”)
- Originally used as communication between pharmacies and payers
- Six REMS programs currently leverage the “switch system” to transmit relevant REMS information
- Used in outpatient pharmacy settings

REMS and Pharmacy Systems



Adoption of “Switch”

Benefits:

- “Switch” evaluates:
  - Prescriber, pharmacy, and patient enrollment
  - Verification of safe-use conditions are met (e.g., lab tests)
- Minimizes disruption of existing workflows
- Integrated with billing process (i.e. Hard Stop) at point of dispense

Challenges:

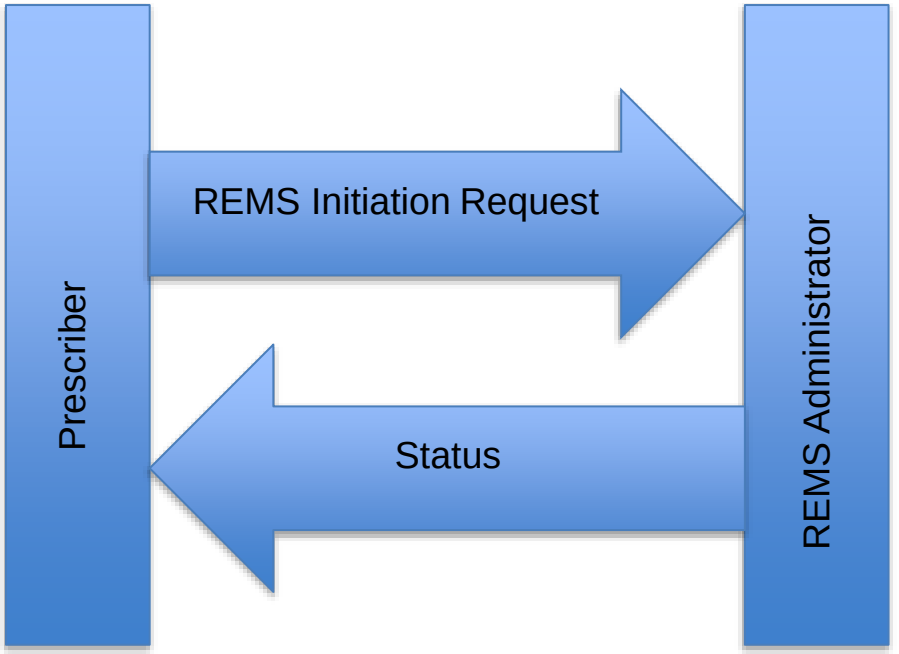
- Each submission to the switch “ping” has an associated cost
- May not be a cost-effective or viable option for other pharmacy settings
- Does not address prescriber workflow

NCPDP Script Standard

- NCPDP SCRIPT Standard (e-Prescribing)
- Transmits prescription & medication information between prescribers, pharmacies, payers, and other entities
- NCPDP SCRIPT Standard Implementation Guide (version 2017071)

REMS and e-Prescribing

- New NCPDP SCRIPT Standard includes REMS transactions:
  - REMS initiation request/response
  - REMS request/response
- The system allows REMS administrators to present prescribers with a “question set” similar to those used in prior authorization



Source: Adapted from NCPDP SCRIPT Standard Implementation Guide Version 2017071

New Version NCPDP Script Standard

- Required for Medicare Part D e-prescribing
- REMS is one transaction named by CMS for use to:
  - promote patient safety
  - enable REMS requirements to be completed within existing healthcare workflow
- Implementation date went into effect January 1, 2020

Adoption of “SCRIPT”

Benefits:	Challenges:
• Allows for real-time verification of safe-use conditions (e.g., lab tests) • Can be integrated in EHR systems • Verification of safe-use conditions can be completed upstream	• Is only required for Medicare Part D e-prescribing • There are different EHR systems • Primarily used to facilitate messages related to ambulatory prescriptions.

What else is FDA doing to further REMS standardization and integration?

- Working with standards development organizations to support further standardization and integration initiatives
- Support adoption of REMS standards by REMS administrators, EHRs, third-party payers, and software vendors
- Evaluate feasibility of REMS Web Portal

REMS Web Portal (REMS-WP)

Request for information (RFI)

Risk Evaluation and Mitigation Strategy (REMS) Web Portal

ACTIVE

Contract Opportunity

Notice ID
FDA-RFI-19-1222277

Related Notice

Department/Ind. Agency
HEALTH AND HUMAN SERVICES, DEPARTMENT OF
Sub-tier
FOOD AND DRUG ADMINISTRATION
Office
FDA OFFICE OF ACQ GRANT SVCS

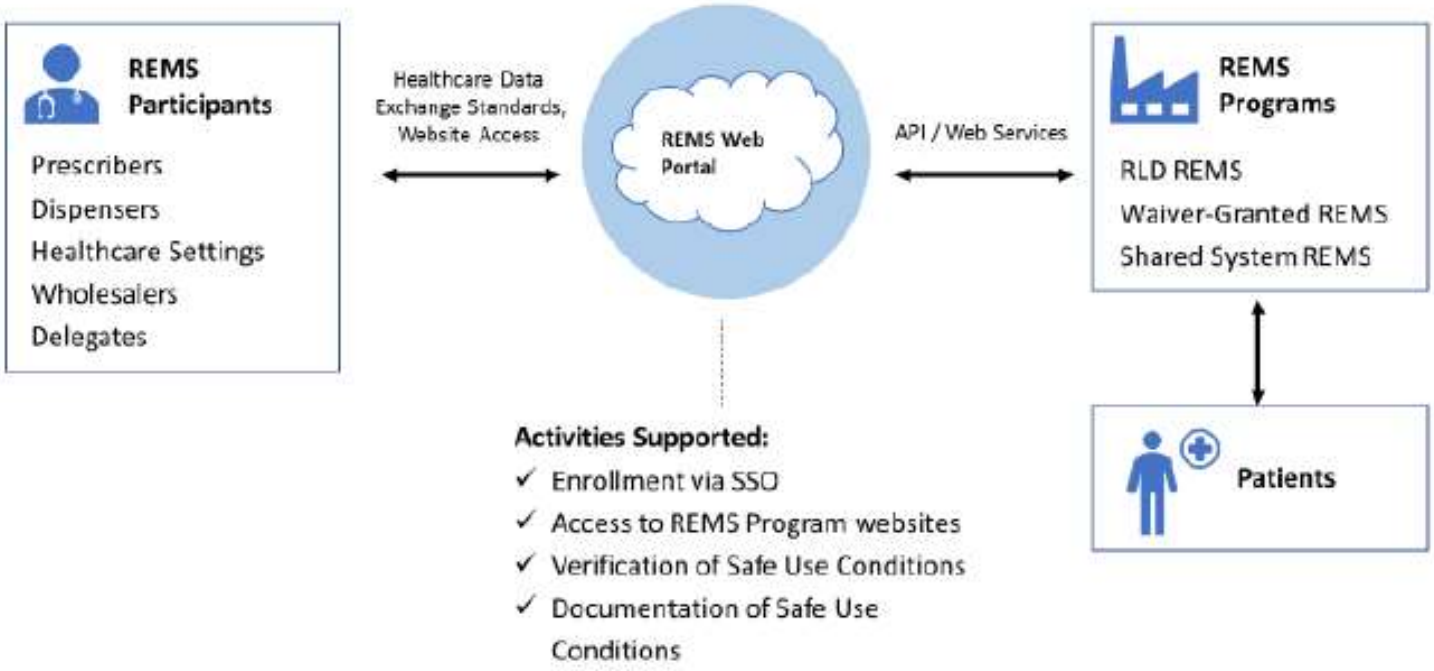
General Information

Contract Opportunity Type: Sources Sought (Original)
All Dates/Times are: (UTC-05:00) EASTERN STANDARD TIME, NEW YORK, USA
Original Published Date: Dec 10, 2019 03:12 pm EST
Original Response Date: Jan 31, 2020 04:00 pm EST
Inactive Policy: 15 days after response date
Original Inactive Date: Feb 15, 2020

- Broaden FDA's understanding of the market's capability to provide a REMS-WP
- Participation and completion of REMS tasks by healthcare providers and patients through the REMS-WP by Single Sign-On (SSO) mechanism
- Allows for data sharing across existing REMS program websites and databases via the REMS-WP platform

https://beta.sam.gov/opp/3c27376564bf4dc88e05e01f00aab5b8/view

REMS-WP Conceptual Model



https://beta.sam.gov/opp/3c27376564bf4dc88e05e01f00aab5b8/view

Challenge Question #3

When designing a REMS, sponsors should consider all of the following, except:

A. Design REMS to be compatible with clinical workflows

B. Seek input from REMS stakeholders

C. Design a REMS that does not leverage Health IT

D. Work with standards development organizations

Next Steps

- FDA has received feedback on the REMS-WP RFI and is currently considering next steps
- FDA is considering future public meeting to prioritize additional REMS standardization projects
- FDA is interested in hearing from sponsors that are interested in implementing REMS standards, such as the NCPDP SCRIPT standard

Summary

- Submit your REMS in SPL to enable integration
- Seek stakeholder input as part of the REMS design and development
- Design your REMS to be compatible with existing health data standards
- FDA is interested to hear from you

Resources

- REMS@FDA
- Format and Content of a REMS Document
- Providing Regulatory Submissions in Electronic Format – Content of the REMS Document Using Structured Product Labeling
- SPL Resources Page
- REMS WP RFI

Questions?

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