REMS and Health Data Standards

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Contents

1. **Introduction to health data standards**
2. Current use of health data standards in REMS
3. FDA's vision for a standards-based "common REMS platform"

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 should REMS standards look like?

1. Collaborative: Developed in consultation with stakeholders
2. Iterative: Not static; evolve as the healthcare system changes and best practices are identified
3. Implementable: Clear and straightforward to implement
4. Flexible: Allow for new and innovative approaches and accommodate a wide range of risks and REMS.
5. Customizable: Not one-size-fits-all; allow for customization to integrate into stakeholder processes.
6. Accessible: Specifically, standards should help "centralize" REMS functions

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

Why are health data standards important for REMS?

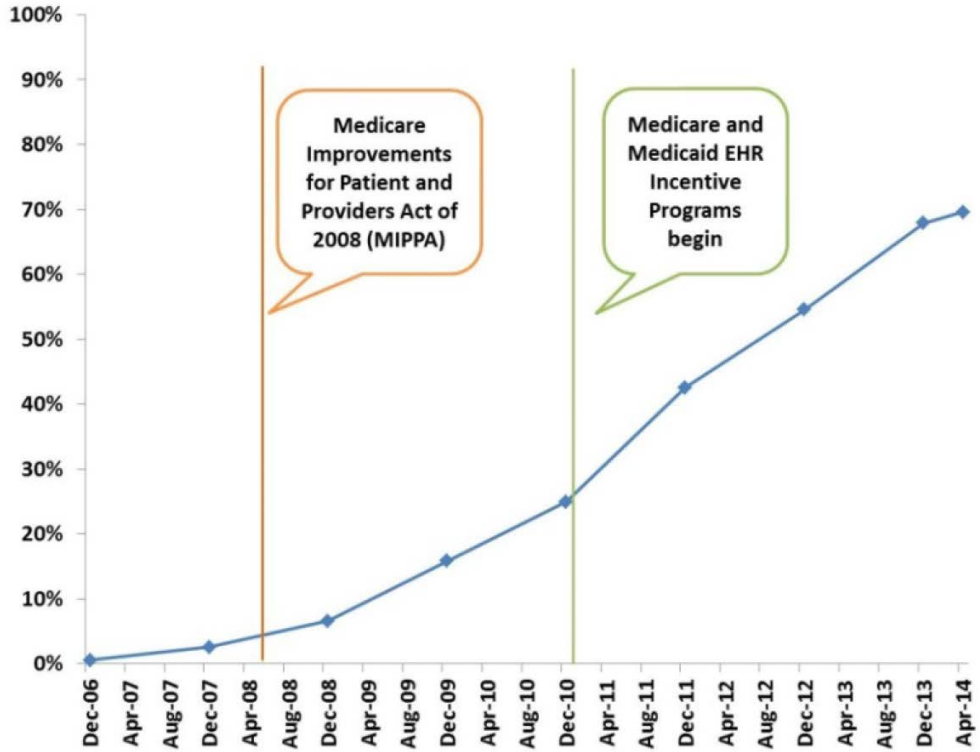
These standards satisfy our REMS standardization “principles” :

1. Collaborative: Developed in a public, inclusive process.
2. Iterative: Revised over time.
3. Implementable: Have detailed implementation guides and experienced implementers.
4. Flexible: Do not dictate *content* – just how information is exchanged; designed to address a wide range of scenarios.
5. Customizable: Designed from the start to be integrated into existing systems.
6. Accessible: Allow different systems to seamlessly share information, allowing it to be centrally accessed.

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. Introduction to health data standards

2. **Current efforts to standardize and integrate REMS using health data standards**

3. FDA's vision for a standards-based "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 Verifying Safe Use Conditions

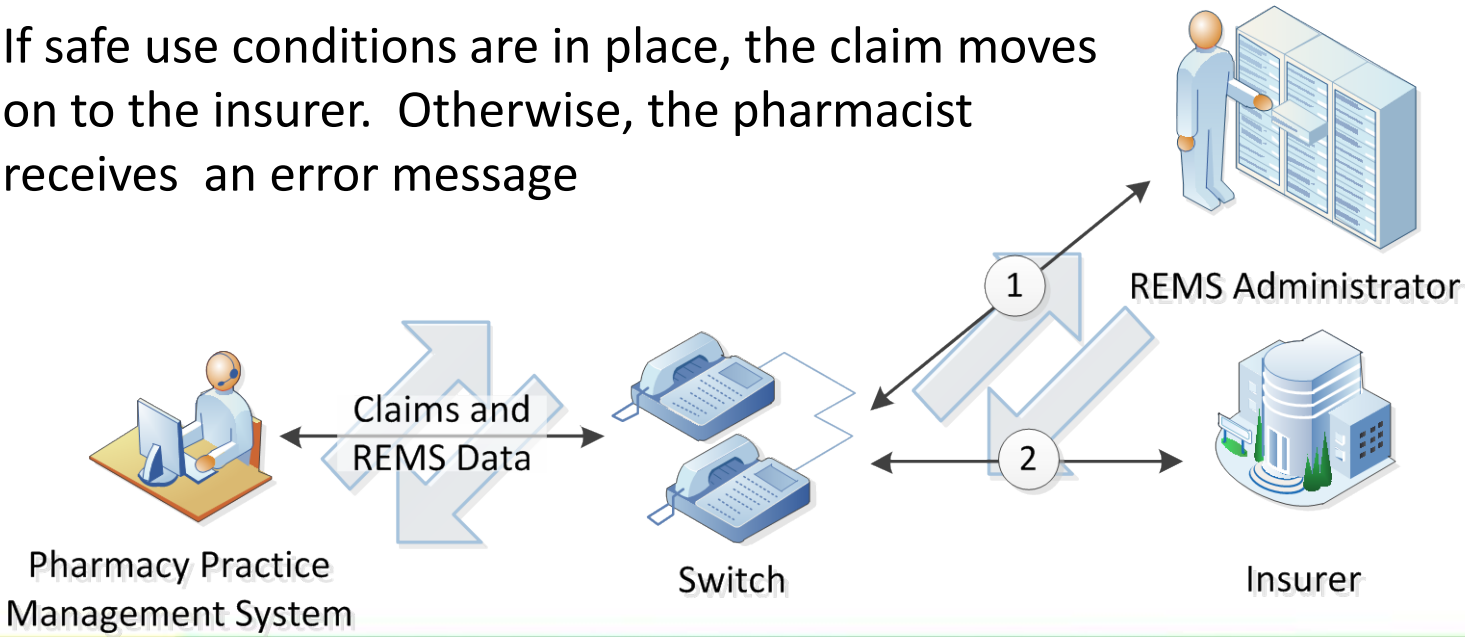
- Pharmacist plays key role in REMS as the last checkpoint before patient receives prescription.
- In many REMS with ETASU, pharmacists are asked to go to a website or call center to verify that certain "safe use conditions" are in place prior to dispensing, for example:
  - Prescriber is enrolled and 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. Introduction to health data standards

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3. **FDA's vision for a standards-based "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.

Our vision: A Common REMS Platform

Standardize REMS by creating a "Common REMS Platform" leveraging health data standards:

1. Establish a set of health data standards for common REMS activities. These would be called "REMS Platform Standards".
2. Share those standards and encourage REMS to become "Platform REMS"
3. Promote the development of tools that leverage these platform standards and give stakeholders a centralized way to interact with Platform REMS.

Establishing Standards
Step 1: Convene Stakeholders

Form a working group of REMS stakeholders including:

- Sponsors and "REMS Administrators"
- Healthcare providers: Prescribers, Pharmacists, dispensers, healthcare institutions
- Patients
- Health IT vendors
- Government partners

Establishing Standards
Step 2: Identify and Develop use cases

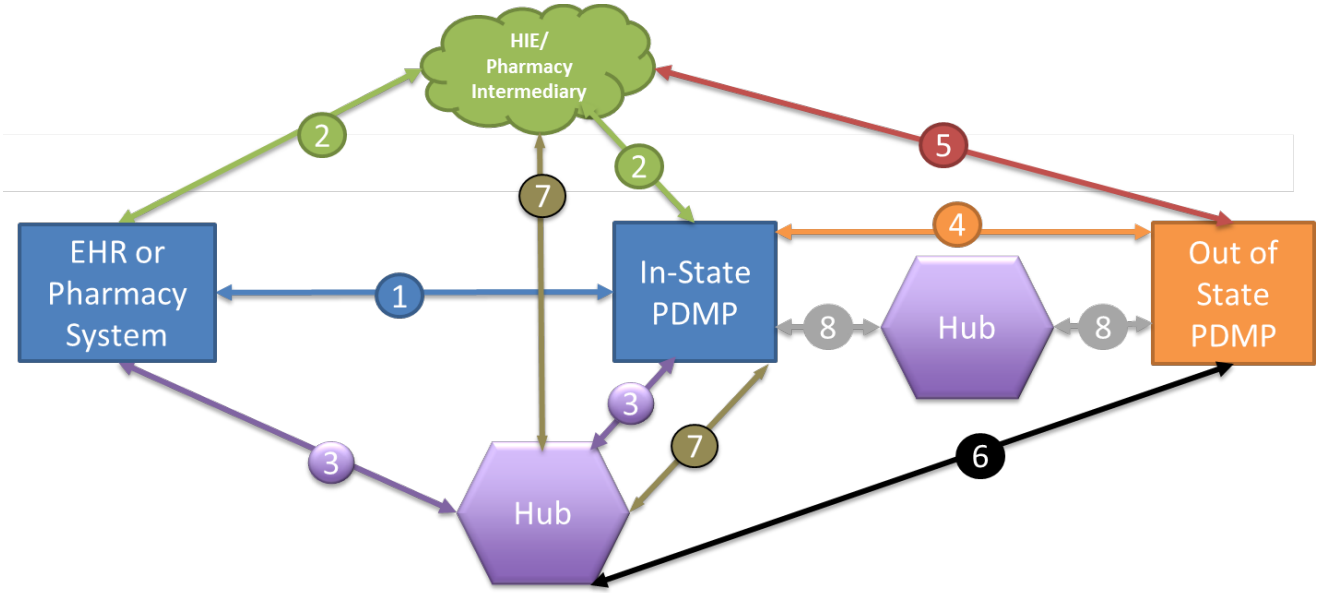
Use Case: A description of the REMS activity to be standardized, how stakeholders and systems interact to perform the activity, and what the standard needs to accomplish.

Possible REMS use cases include:

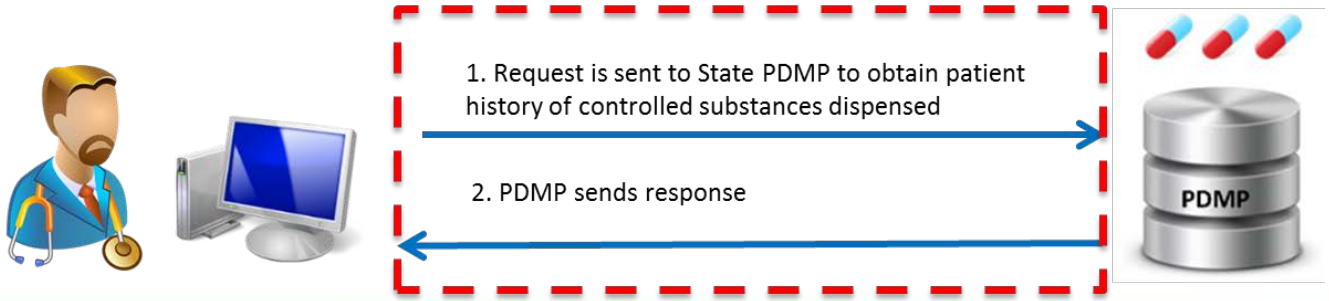
- Healthcare Provider Enrollment and Certification
- Patient Enrollment and Agreement
- Documentation of Safe Use Conditions by the Prescriber
- Verification of Safe Use Conditions by the Dispenser

Establishing Standards
Step 2: Identify and Develop use cases

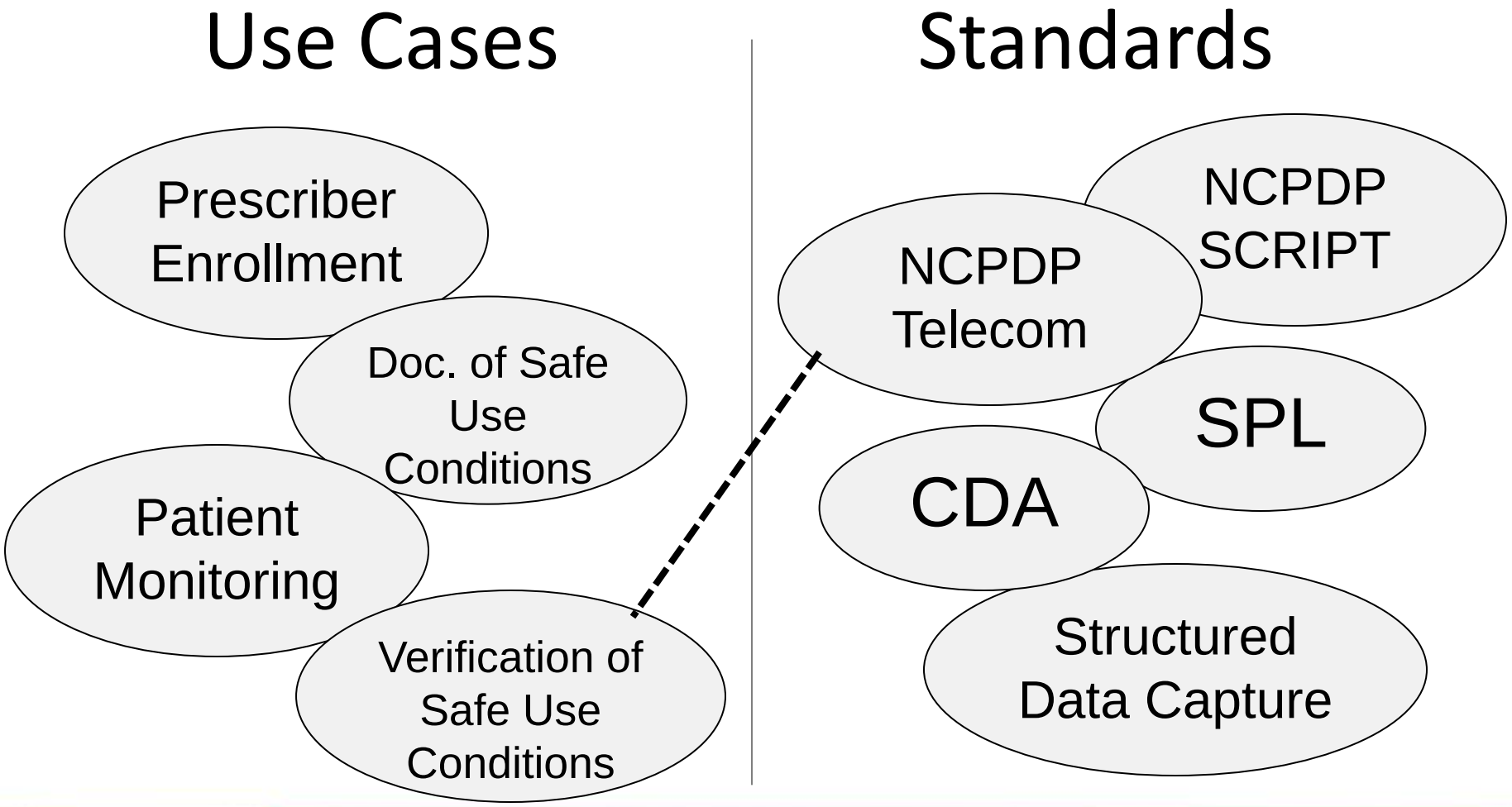
Use Case Diagram



User Story



Establishing Standards
Step 3: Identify Standards and pilot them



Establishing Standards
Step 4: Develop Implementation Guides

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.

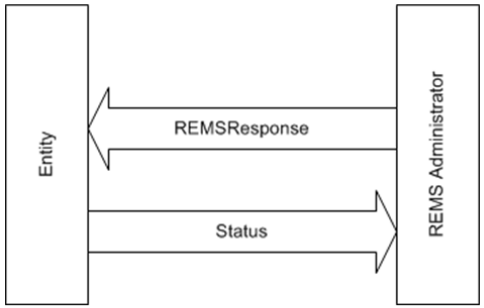


Figure 43x. REMSRequest Flow

Step 5: Establish Platform Standards

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

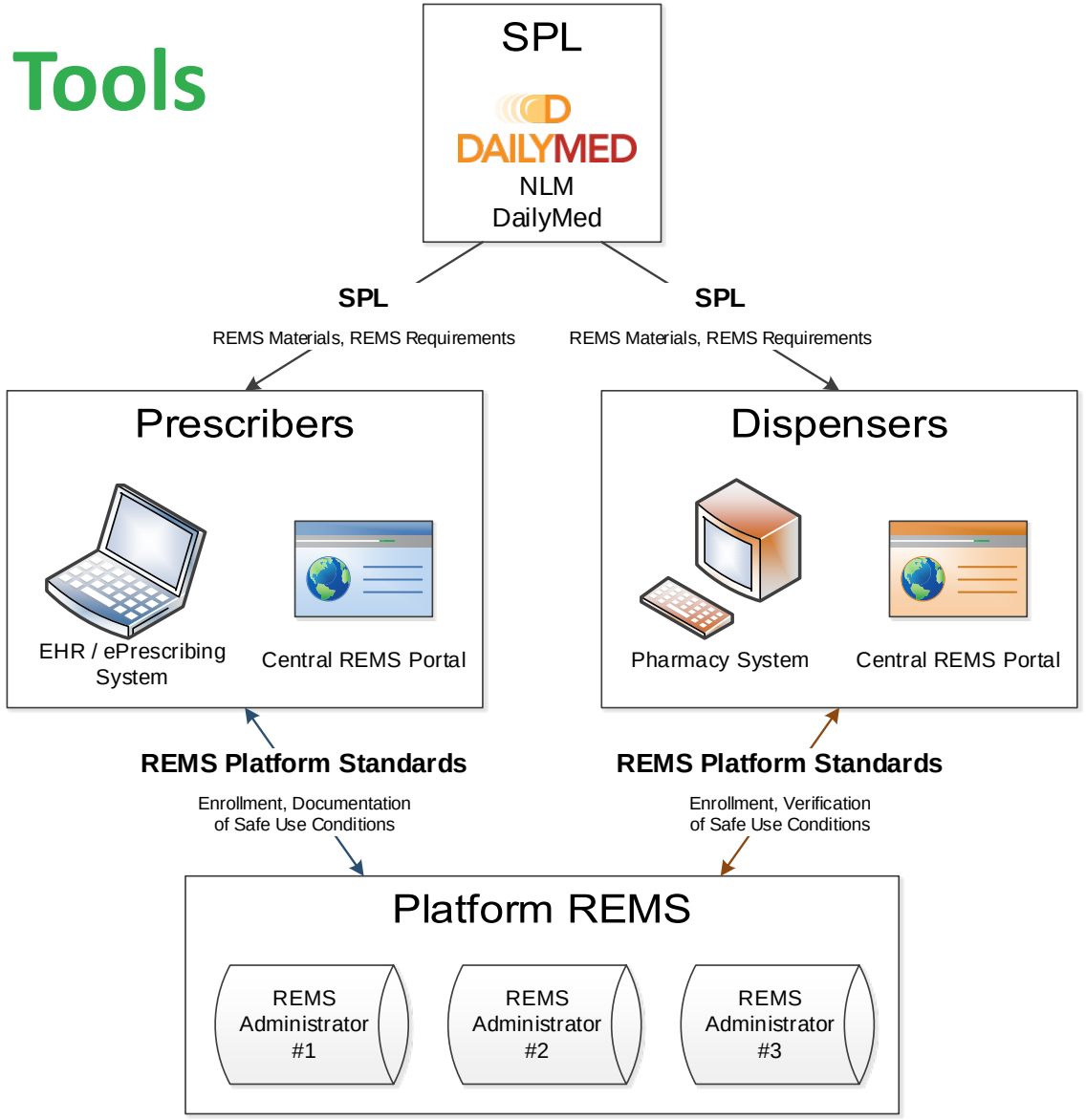
This table contains a listing of the data exchange, file formats and terminology standards supported at FDA. These standards have gone through all the steps necessary to make this part of the regulatory review process, including posting of regulatory guidance documents and associated implementation guidelines 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.

Step 6: Develop Tools

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

Next Steps

- FDA plans to work towards…
  - Identifying initial use cases for further development
  - Working with stakeholders to help identify and pilot appropriate standards
  - Establishing an approach for sharing “platform standards” with the public
- We welcome stakeholder feedback on how to best achieve a “Common REMS Platform”