Update on REMS Assessment and Standardization Initiatives

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Office of Surveillance and Epidemiology
U.S. Food and Drug Administration

Outline

- **Update on initiatives to modernize and improve REMS assessments**
- Update on initiatives to standardize and integrate REMS
  - Format and Content of a REMS Document Guidance (FINAL)
  - REMS Document Technical Conformance Guide (FINAL) and Structured Product Labeling (SPL)
  - REMS SPL submissions
  - REMS Integration, Innovation, and Modernization project

REMS authorities to require assessments

- When the REMS authorities were put into place, FDA for the first time could require sponsors to conduct an assessment of their risk mitigation strategy
  - 18 months, 3 years, and in the 7th year after the strategy is initially approved
  - At a frequency specified in the strategy; can be increased or reduced in frequency, and eliminated under certain circumstances
- The statute did not specifically describe how a sponsor should conduct an assessment.
  - Section 505-1(g)(3) of the FDCA specifies that a REMS assessment shall include **an assessment of the extent to which the REMS is meeting the goal or whether ~~1~~ one or more such goals or such elements should be modified**

REMS assessment challenges

We are not always able to determine if the REMS are meeting goals and the reasons are likely multifactorial:

- REMS may not be designed to measure whether they have achieved the expected outcome
- REMS assessments do not always include the information needed to determine if REMS is meeting its goals
- No pre-specification prior of threshold for success
- Over reliance on process measures

REMS GOAL

Modernizing and improving REMS assessments

- In 2020, FDA launched a multi-year effort to modernize and improve REMS Assessments with the goal of improving the quality of information used to assess the effectiveness of REMS, taking action on REMS that are not meeting their risk mitigation goals, and improving the efficiency of FDA's review of those reports.
- In 2022, FDA committed to modernize and improve REMS assessments by incorporating REMS assessment planning into the design of REMS, clarifying its expectations regarding methods to evaluate the performance of REMS, increasing the efficiency of FDA's review of REMS assessment reports, and establishing FDA performance goals for review of REMS assessment methods and study protocols.

*REMS Assessment Commitments |PDUFA VII Commitments | Fiscal Years 2023 – 2027

REMS Assessment Commitments |PDUFA VII Commitments | Fiscal Years 2023 – 2027*

Establish FDA review performance goals to review and notify sponsor with concurrence or comments within 90 days of receipt for 50% of REMS assessment methods and protocols (50% in FY24; 70% in FY25; 90% FY26 and FY27)

Update relevant guidances to incorporate REMS assessment planning into the design of REMS by providing recommendations regarding: 1) linking the design with the assessments 2) ensuring sufficient and appropriate data collection, and 3) identifying key metrics for success (e.g., primary and secondary)

Develop draft guidance regarding the format and content of a REMS assessment report, including the type of data that can support elimination of a REMS

Update existing policies and procedures for reviewing methodological approaches and study protocols used to assess a REMS program

Issue new or update existing policies and procedures to determine if modifications to the REMS or revisions to the REMS assessment plan are needed

**Language on this slide is not verbatim from commitment letter*

PDUFA VII: Fiscal Years 2023 – 2027 | FDA

Progress on meeting the review performance goals

We are currently building a framework to support the implementation of the new performance goals, including:

- Drafting a new MAPP on the Review of Assessment Methodology and Study Protocols
- Updating Form 356H to include a specific box for submission of REMS Assessment Methodology
- Creating new communication templates
- Hiring additional analysts

Sponsors should prominently identify the submission containing the assessment instruments and methodology with the following wording in bold capital letters at the top of the first page of the submission:

NDA/BLA ###### REMS ASSESSMENT METHODOLOGY

(insert concise description of content in bold capital letters, e.g.,

ASSESSMENT METHODOLOGY, PROTOCOL, SURVEY METHODOLOGIES, AUDIT PLAN, DRUG USE STUDY)

Progress on assessment guidances

Update relevant guidances to incorporate REMS assessment planning into the design of REMS by providing recommendations regarding: 1) linking the design with the assessments 2) ensuring sufficient and appropriate data collection, and 3) identifying key metrics for success (e.g., primary and secondary)

Develop draft guidance regarding the format and content of a REMS assessment report**, including the type of data that can support elimination of a REMS**

Finalization or updates to the following draft guidances:

- REMS Assessments: Planning and Reporting*
- Survey Methodologies to Assess REMS Goals that Relate to Knowledge

New:

- Format and Content of a REMS Assessment Report*

*User fee deliverable – Currently discussing if guidance commitments will be met by updating or issuing new guidances.

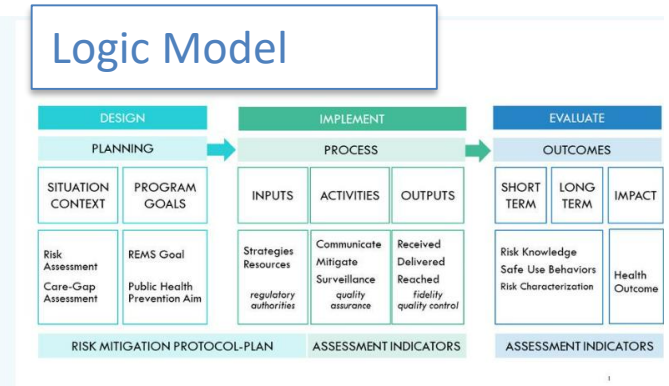
Progress on policies and procedures

Issue new or update existing policies and procedures to determine if modifications to the REMS or revisions to the REMS assessment plan are needed

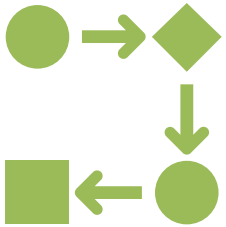
Plan is to:

- Update MAPP 6702.1 Risk Evaluation and Mitigation Strategy (REMS) Assessment
- Review other MAPPs to determine if updates are needed

New training has been developed for staff involved in REMS reviews



The training includes a framework to link the design of a REMS to the assessment.



This framework can help clarify the relationship between the objectives, strategies and evaluation of a REMS

We are gaining experience using this framework

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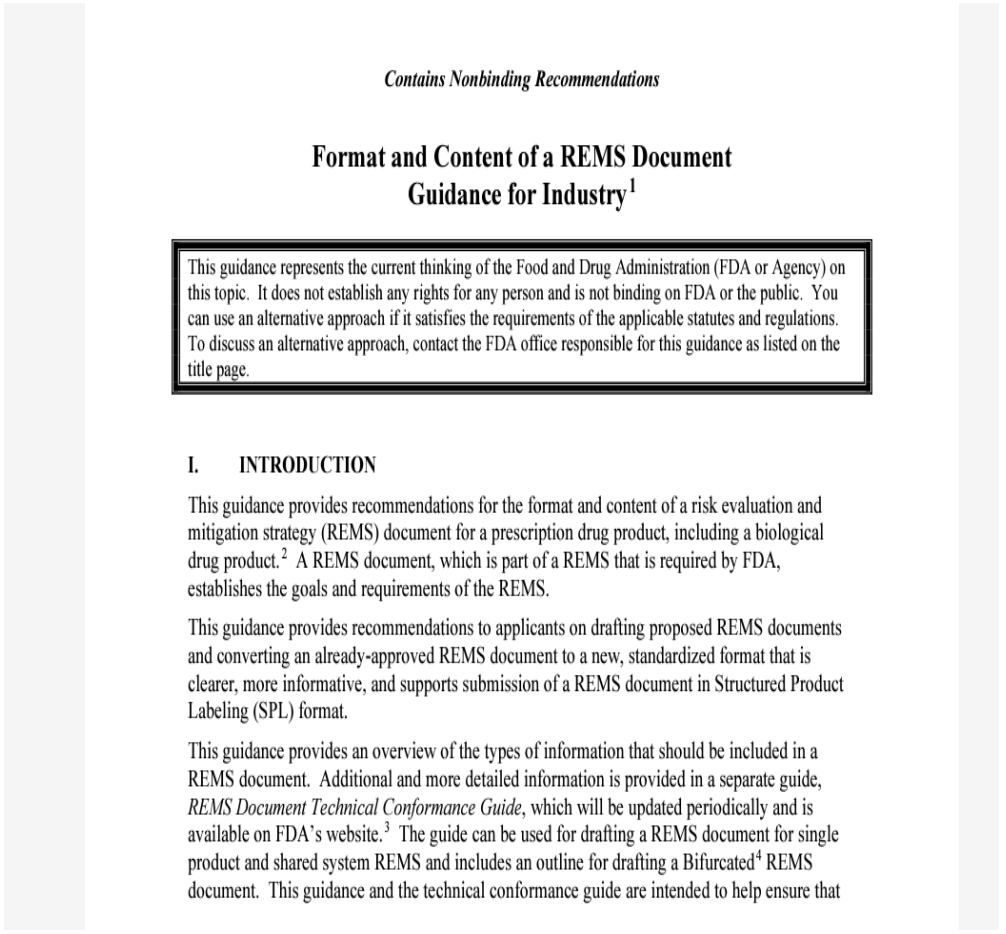
GFI: Format and Content of a REMS Document

- This final guidance, published in January 2023, provides recommendations for the format and content of a REMS document.
  - The draft guidance was published in 2017
- The goals of the revisions to the guidance were to:
  - To share what we have learned since 2017, so applicants are better able to draft a REMS Document
  - To decouple the REMS Document Template from the Guidance so we can update the template periodically
  - To provide applicants the most up-to-date information in tandem with the requirement to submit for applicants to submit the REMS Document in SPL format



Contains Nonbinding Recommendations

Format and Content of a REMS Document
Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance provides 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.[2] A REMS document, which is part of a REMS that is required by FDA, establishes the goals and requirements of the REMS.

This guidance provides recommendations to applicants on drafting proposed REMS documents and converting an already-approved REMS document to a new, standardized format that is clearer, more informative, and supports submission of a REMS document in Structured Product Labeling (SPL) format.

This guidance provides an overview of the types of information that should be included in a REMS document. Additional and more detailed information is provided in a separate guide, *REMS Document Technical Conformance Guide*, which will be updated periodically and is available on FDA's website.[3] The guide can be used for drafting a REMS document for single product and shared system REMS and includes an outline for drafting a Bifurcated[4] REMS document. This guidance and the technical conformance guide are intended to help ensure that

What changes were made?

Overall, there are no sweeping changes to the REMS document format or the guidance

- ✓ Separated the REMS document template from the guidance
- ✓ Updated to reference “packaging and disposal” authority
- ✓ Addressed docket comments
- ✓ Updated language in the guidance to align with changes to the REMS Document Template
- ✓ Update links
- ✓ Verify information is consistent with other, current guidances

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Guidance: F&C REMS Document (final)

REMS Document **Technical Conformance Guide**

What is published?

1. Guidance: Format & Content of a REMS Document (final)
2. **REMS Document Technical Conformance Guide**
   A. **REMS Document Template**
   B. **Bifurcated REMS Document Outline**

Published in January 2023

REMS Document Technical Conformance Guide template verses REMS Document in SPL†

REMS Document

Risk Evaluation and Mitigation Strategy (REMS) Document
[PROPRIETARY[7] (established/proper name) or
[Established/Proper/Class Name] [Shared System] REMS

I. Administrative Information

Risk: [risk REMS is designed to address.]
Application Number(s): NDA/BLA [application number(s)] (and Authorized Generic)
Application Holder: [applicant name]
Initial [Shared System] REMS Approval: [MM/YYYY]
Most Recent REMS Update: [MM/YYYY]

II. REMS Goal(s)

[Overall REMS goal]
1. [REMS objective]
2. [Other REMS objectives, as needed]

III. REMS Requirements

[Applicant] must ensure that [health care providers/health care settings/patients/pharmacies/wholesalers-distributors] comply with the following requirements:

1. Health care providers who prescribe [proprietary/established/proper/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 the Prescriber Educational Material(s)]. 4. Take the [REMS Material] training provided by the [entity providing the training]. 5. Successfully complete the [Knowledge Assessment] and submit it to the REMS. 6. Enroll by completing and submitting the [Enrollment Form] to the REMS.
Before treatment initiation (at specified interval)	7. Counsel the patient using [REMS Material]. 8. Assess the patient's [condition(s) or health status(es)]. 9. Assess the patient for [adverse event]. 10. Complete the [Patient Form]. Provide a completed copy of the form to the patient. 11. Enroll the patient by completing and submitting the [applicable enrollment forms] [List all Enrollment Forms] to the REMS.

[7] [PROPRIETARY NAME] includes [list the dosage forms] and applicable authorized generics.

REMS Title →

I. Administrative Information →

II. REMS Goals →

III. REMS Requirements →

REMS Document in SPL

Risk Evaluation and Mitigation Strategy (REMS) Document
[PROPRIETARY* (established/proper name)] or [Established/Proper/Class Name] [Shared System] REMS

I. ADMINISTRATIVE INFORMATION

THIS SAMPLE SHOULD NOT BE USED IN PLACE OF THE SPL IMPLEMENTATION GUIDE AND VALIDATION PROCEDURES AND MAY OR MAY NOT BE UPDATED WHEN THE IMPLEMENTATION GUIDE CHANGES

Risk: [risk REMS is designed to address.]

Application Number(s): NDA/BLA [application number(s)] (and Authorized Generic)

Application Holder: [applicant name]

Initial [Shared System] REMS Approval: [MM/YYYY]

Most Recent REMS Update: [MM/YYYY]

II. REMS Goal(s)

[Overall REMS goal]
1. [REMS objective]
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III. REMS Requirements

[Applicant] must ensure that [health care providers/health care settings/patients/pharmacies/wholesalers-distributors] comply with the following requirements:

1. Healthcare Providers who prescribe [proprietary/established/proper/class name] must:

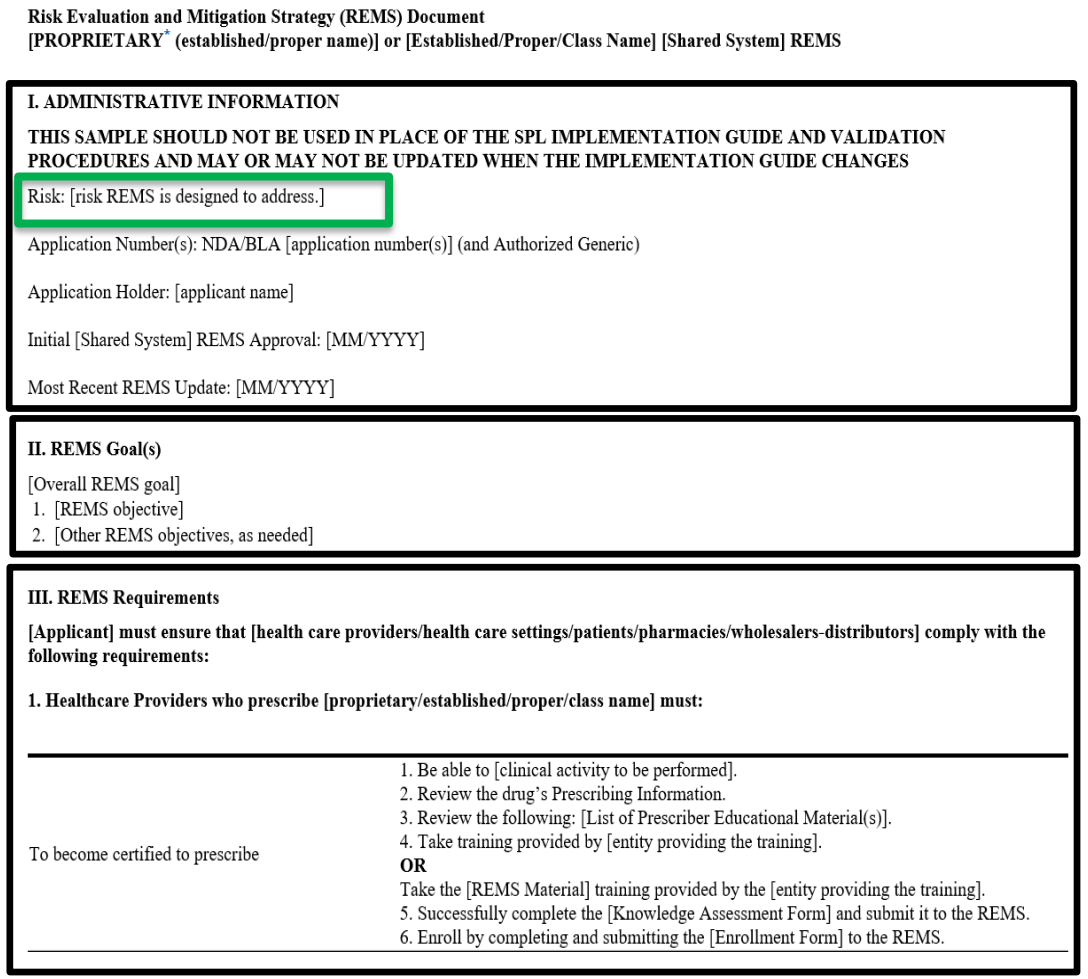
To become certified to prescribe	1. Be able to [clinical activity to be performed]. 2. Review the drug's Prescribing Information. 3. Review the following: [List of Prescriber Educational Material(s)]. 4. Take training provided by [entity providing the training]. **OR** Take the [REMS Material] training provided by the [entity providing the training]. 5. Successfully complete the [Knowledge Assessment Form] and submit it to the REMS. 6. Enroll by completing and submitting the [Enrollment Form] to the REMS.

† Structured Product Labeling (SPL) is a document markup standard approved by Health Level Seven (HL7®) and adopted by FDA as a mechanism for exchanging product, facility, and REMS information

REMS Document Technical Conformance Guide template corresponds to REMS Document SPL section codes

New!

REMS Document in SPL



Risk Evaluation and Mitigation Strategy (REMS) Document
[PROPRIETARY* (established/proper name)] or [Established/Proper/Class Name] [Shared System] REMS

I. ADMINISTRATIVE INFORMATION

THIS SAMPLE SHOULD NOT BE USED IN PLACE OF THE SPL IMPLEMENTATION GUIDE AND VALIDATION PROCEDURES AND MAY OR MAY NOT BE UPDATED WHEN THE IMPLEMENTATION GUIDE CHANGES

Risk: [risk REMS is designed to address.]

Application Number(s): NDA/BLA [application number(s)] (and Authorized Generic)

Application Holder: [applicant name]

Initial [Shared System] REMS Approval: [MM/YYYY]

Most Recent REMS Update: [MM/YYYY]

II. REMS Goal(s)

[Overall REMS goal]
1. [REMS objective]
2. [Other REMS objectives, as needed]

III. REMS Requirements

[Applicant] must ensure that [health care providers/health care settings/patients/pharmacies/wholesalers-distributors] comply with the following requirements:

1. Healthcare Providers who prescribe [proprietary/established/proper/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. Take training provided by [entity providing the training]. **OR** Take the [REMS Material] training provided by the [entity providing the training]. 5. Successfully complete the [Knowledge Assessment Form] and submit it to the REMS. 6. Enroll by completing and submitting the [Enrollment Form] to the REMS.

I. Administrative Information
(87523-7)

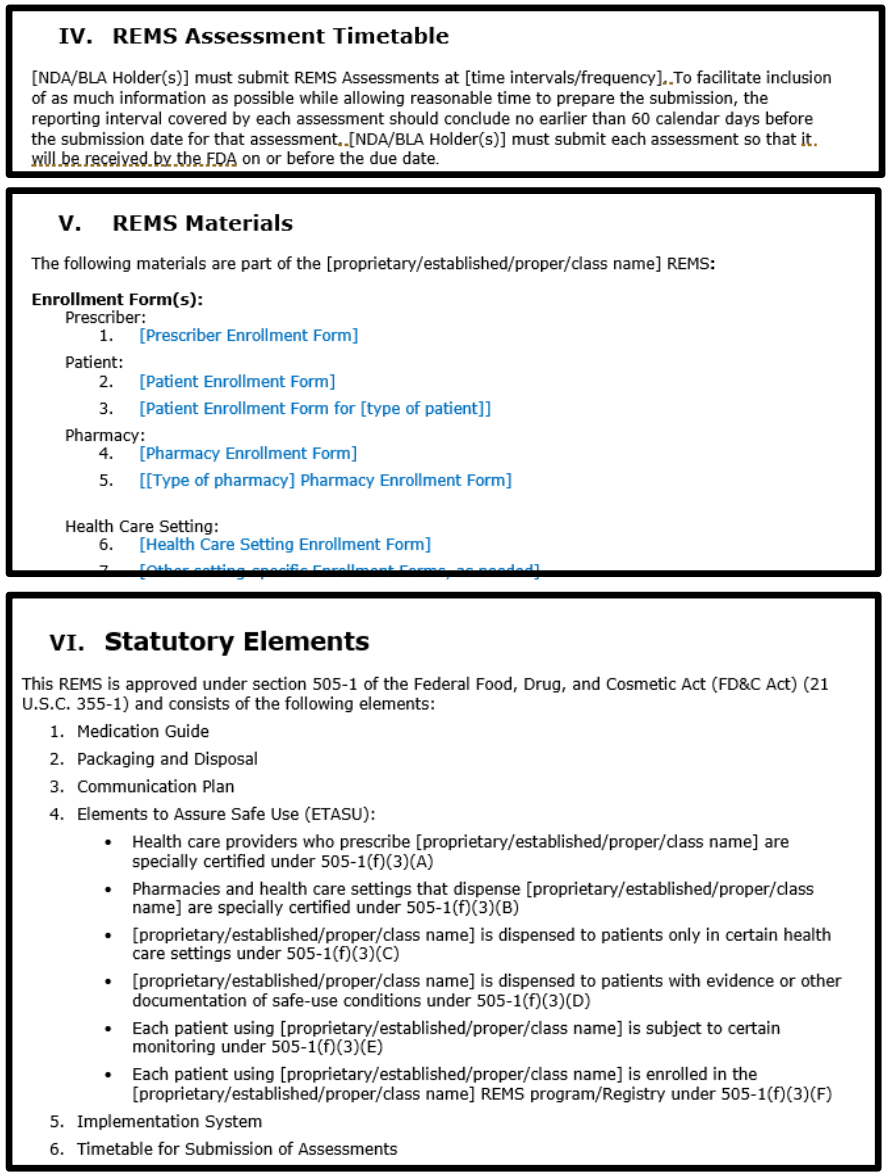
II. REMS Goals
(82349-2)

III. REMS Requirement
(87524-5)

Section Headings: https://www.fda.gov/industry/structured-product-labeling-resources/section-headings-loinc

REMS Document Technical Conformance Guide template corresponds to REMS Document SPL section codes

REMS Document in SPL



IV. REMS Assessment Timetable

[NDA/BLA Holder(s)] must submit REMS Assessments at [time intervals/frequency]. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. [NDA/BLA Holder(s)] must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the [proprietary/established/proper/class name] REMS:

Enrollment Form(s):

Prescriber:
1. [Prescriber Enrollment Form]

Patient:
2. [Patient Enrollment Form]
3. [Patient Enrollment Form for [type of patient]]

Pharmacy:
4. [Pharmacy Enrollment Form]
5. [[Type of pharmacy] Pharmacy Enrollment Form]

Health Care Setting:
6. [Health Care Setting Enrollment Form]

VI. Statutory Elements

This REMS is approved under section 505-1 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355-1) and consists of the following elements:

1. Medication Guide
2. Packaging and Disposal
3. Communication Plan
4. Elements to Assure Safe Use (ETASU):
   - Health care providers who prescribe [proprietary/established/proper/class name] are specially certified under 505-1(f)(3)(A)
   - Pharmacies and health care settings that dispense [proprietary/established/proper/class name] are specially certified under 505-1(f)(3)(B)
   - [proprietary/established/proper/class name] is dispensed to patients only in certain health care settings under 505-1(f)(3)(C)
   - [proprietary/established/proper/class name] is dispensed to patients with evidence or other documentation of safe-use conditions under 505-1(f)(3)(D)
   - Each patient using [proprietary/established/proper/class name] is subject to certain monitoring under 505-1(f)(3)(E)
   - Each patient using [proprietary/established/proper/class name] is enrolled in the [proprietary/established/proper/class name] REMS program/Registry under 505-1(f)(3)(F)
5. Implementation System
6. Timetable for Submission of Assessments

IV. REMS Assessment Timetable
(82349-2)

V. REMS Materials
(82346-8)

VI. Statutory Elements
(82348-4)

New!

Section Headings: https://www.fda.gov/industry/structured-product-labeling-resources/section-headings-loinc

REMS Document Technical Conformance Guide includes Bifurcated REMS Document Outline

New!

Appendix B: Bifurcated REMS Document Outline

Risk Evaluation and Mitigation Strategy (REMS) Document

This is the template for a Bifurcated REMS Document. A Bifurcated REMS Document is used when the approval of a shared system REMS may coincide with tentative approval of an ANDA or section 505(b)(2) application. For more information, refer to the Guidance for Industry, *Development of a Shared System or Separate Comparable REMS,* available at https://www.fda.gov/media/113869/download.

A Bifurcated REMS, is a single REMS consisting of two parts:

(Part A) The currently approved REMS for the applicable listed drug, which remains in effect until the first ANDA that references the reference listed drug or section 505(b)(2) application that relies upon the listed drug receives full approval, and

(Part B) The Shared System REMS, which is implemented upon full approval of the first ANDA that references the reference listed drug or section 505(b)(2) application that relies upon the listed drug.

A. [PROPRIETARY NAME][8,9] REMS

I. Administrative Information

Retain the text that apply to your REMS and delete the text that does not apply.

Risk: [risk REMS is designed to address]
Application Number(s): NDA/BLA [application number(s)] Use this only for single-applicant REMS. Add (and Authorized Generic) after the corresponding NDA number.
Application Holder: [applicant name] Use this only for single-applicant REMS.
Initial REMS Approval: [MM/YYYY] Initial approval of the REMS for the reference listed drug.
Most Recent REMS Update: [MM/YYYY] Enter the date of the most recent REMS Revision or approved Modification. If there are no updates since the initial approval, delete the text.

II. REMS Goal(s)

[Add goals here]

III. REMS Requirements

[Applicant] must ensure that [List the participants who have requirements under this REMS in the order they appear in this section e.g., **health care providers/pharmacies/health care settings/patients/wholesalers-distributors] comply with the following requirements:**

[8] [PROPRIETARY NAME] includes [list the dosage forms and applicable authorized generics].
[9] The [PROPRIETARY NAME]-specific requirements contained in this document apply until the date of full approval of the first [abbreviated new drug application (ANDA)/505(b)(2) application] joining a shared system REMS with [PROPRIETARY NAME].

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The requirements of the shared system REMS for [Drug Class or Established/Proper Name] apply as of the date of full approval of the first Abbreviated New Drug Application (ANDA) joining a shared system with [PROPRIETARY NAME]

B. [Drug Class or Established/Proper Name] Shared System REMS

I. Administrative Information

Retain the text that apply to your REMS and delete the text that does not apply.

Risk: [risk REMS is designed to address]
Initial Shared System REMS Approval: [MM/YYYY]
Most Recent REMS Update: [MM/YYYY] Enter the date of the most recent REMS Revision or approved Modification. If there are no updates since the initial approval, delete the text.

II. REMS Goal(s)

[Add goals here]

III. REMS Requirements

[Drug Class or Established/Proper Name] Applicants must ensure that [List the participants who have requirements under this REMS in the order they appear in this section e.g., **health care providers/pharmacies/health care settings/patients/wholesalers-distributors] comply with the following requirements:**

1. Health care Providers who prescribe [Drug Class or Established/Proper Name] must:
1.
2. Patients who are prescribed [Drug Class or Established/Proper Name]:
1.

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  - REMS Integration, Innovation, and Modernization project

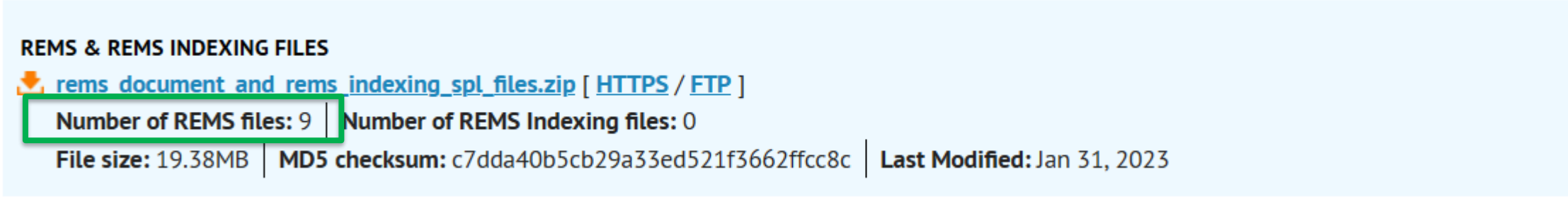
REMS SPL Submissions to FDA‡

- **WHEN:**
  - ***NOW!***
- **WHO:**
  - Applicants must submit their REMS document electronically using SPL
- **WHAT:**
  - All REMS documents submitted to FDA on or after December 28, 2022, must be in SPL format, which include:
    - REMS documents associated with a **new** REMS
    - REMS documents submitted as part of REMS **modifications**
    - REMS documents that are **already in SPL format** must remain in SPL format
  - Components of a REMS required to be filed in SPL format:

Component of a REMS Submission	Submitted in SPL Format?
REMS document	Yes
REMS supporting document	No
REMS materials	Referenced in SPL file (see Structured Product Labeling Implementation Guide with Validation Procedures at https://www.fda.gov/media/84201/download)

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

REMS SPL submissions as of January 31, 2023

- 8 REMS SPLs
- 1 shared system REMS SPL
- National Library of Medicine (NLM) DailyMed website:
  - https://dailymed.nlm.nih.gov/dailymed/spl-resources-all-indexing-files.cfm
  - 

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REMS Modernization through Integration and Standardization

REMS – Current State

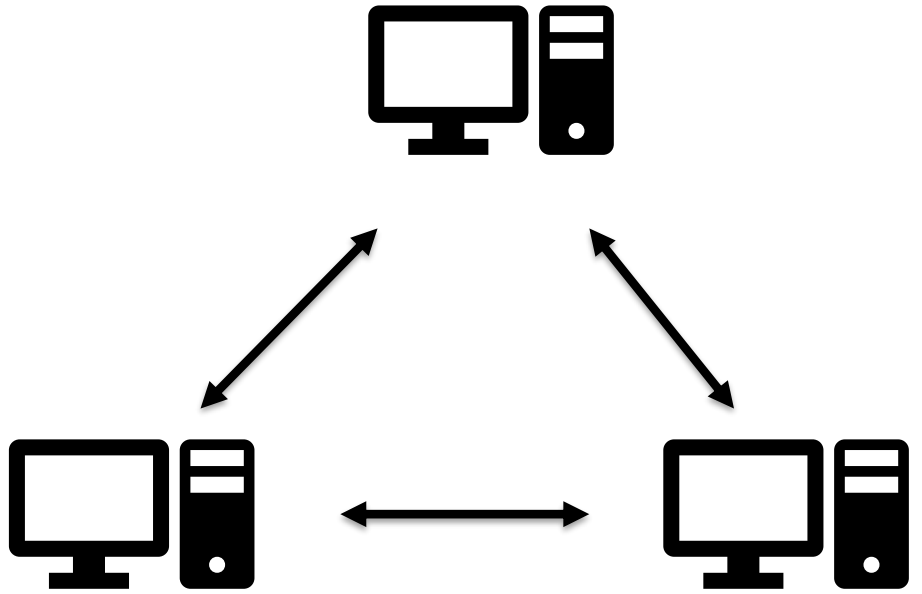
- Manual phone and fax implementation
- Not integrated into prescriber and pharmacist workflow
- Suboptimal patient engagement and transparency
- Lack of quality standardized data for feedback and evaluation
- No unified way to share data between REMS stakeholders
- Delays in therapy for patients and suboptimal care for the patient

REMS – Future State

- Automated, low burden implementation
- Integrated into clinician workflow
- Patients complete requirements, report & monitor status through apps
- Standardized, quality data for timely feedback and more robust evaluations
- Reduced friction in exchange of REMS data
- Patients safely use their medications and achieve timely access to them

Role of health data standards in REMS Integration

- Automated interoperable exchange of standardized REMS data is a key component
- FDA works with established standards development organizations (SDOs)
- Health data standards currently in place in health care are developed by SDOs, including groups such as:
  - National Council for Prescription Drug Programs (NCPDP)
    - SCRIPT version 2017071 adopted by CMS as the US ePrescribing data standard
    - SCRIPT allows for 4 REMS transactions, but they have not been adopted by ePrescribing vendor systems
  - Health Level 7 (HL7®) International
    - REMS SPL data standard
    - Fast Healthcare Interoperability Resources (FHIR®)



HL7® FHIR® Accelerator

FDA

http://hl7.org/CodeX

A Member-driven **community** accelerating **interoperable** data modeling and **implementation** around the **FHIR®** and **mCODE™** HL7® standards, leading to **substantial improvements** in **health care** and **research** in cancer and beyond

Slide adapted from the CodeX™ Master Slide Deck titled, "Introduction to mCODE™ and the CodeX™ HL7® FHIR® Accelerator" available on the CodeX™ Confluence page.

CodeX™ Members

(February 2023)

CodeX Founders ★

PREMIER

AMERICAN ASSOCIATION of PHYSICISTS IN MEDICINE ★
ASTRO AMERICAN SOCIETY FOR RADIATION ONCOLOGY ★
HL7 International ★
Pfizer ★
ALLIANCE FOR CLINICAL TRIALS IN ONCOLOGY ★
MITRE ★
EVERNORTH℠
Syntropy ★
ontada
UnitedHealthcare® ★

PRINCIPAL

Cancer Action Network℠ American Cancer Society® ★
Epic
varian A Siemens Healthineers Company

BENEFACTOR

CIBMTR® CENTER FOR INTERNATIONAL BLOOD & MARROW TRANSPLANT RESEARCH ★
ASCO® AMERICAN SOCIETY OF CLINICAL ONCOLOGY KNOWLEDGE CONQUERS CANCER
Medtronic
TEMPUS
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GOVERNMENT AGENCY

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FDA U.S. FOOD & DRUG ADMINISTRATION
University of Nebraska Medical Center BREAKTHROUGHS FOR LIFE®
MCSP MICHIGAN CANCER SURVEILLANCE PROGRAM

SPONSORED MEMBER

AMGEN®
COMP Canadian Organization of Medical Physicists
OCPM Organisation canadienne des physiciens médicaux
cdisc
NRG ONCOLOGY Advancing Research. Improving Lives.™
SIIM

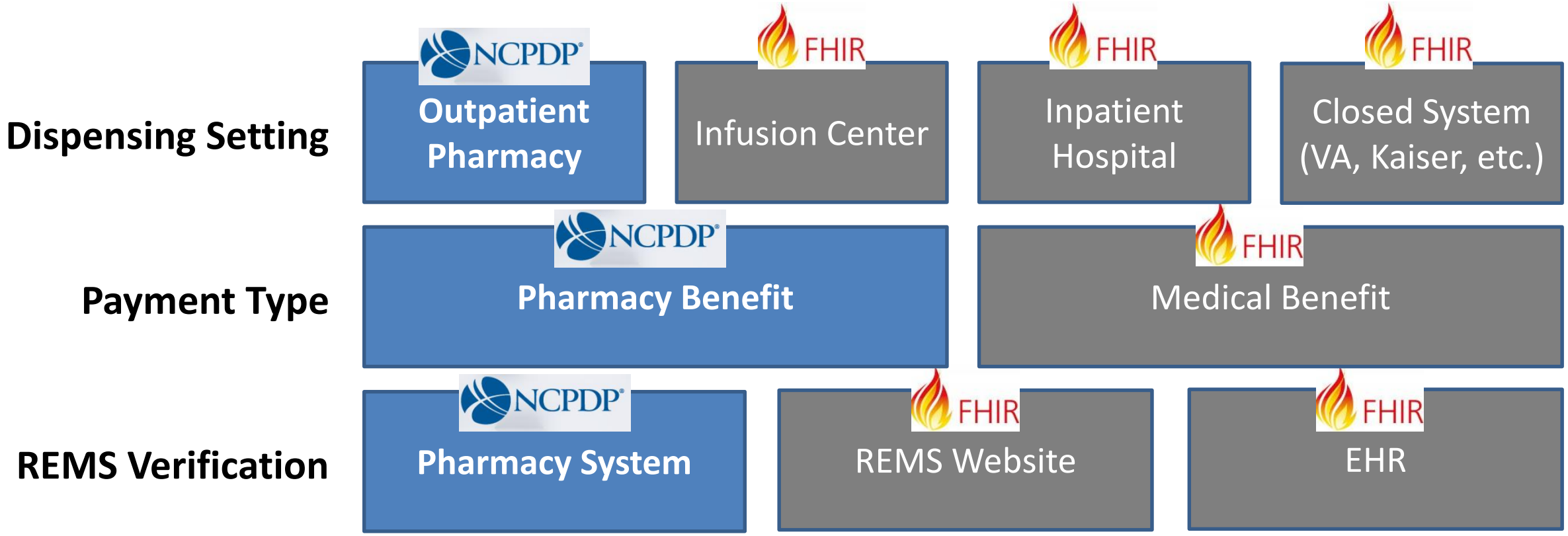
DEVELOPER/IMPLEMENTER

Cancer Insights
CENTANNI PARK
edifecs
Mettle SOLUTIONS
elimu informatics
GuidelineCentral®
MASSIVEBIO
mcg
Navigate Oncology
NeuralFrame
Oncora MEDICAL
patientlink Better Patient Connection · Better Data Collection
PHENOTIPS
PRINCIPIA HEALTH SCIENCES
QL HC Quantum Leap Healthcare Collaborative
storyhealth
Wemedoo Clinical Information Specialists

Slide adapted from the CodeX™ Master Slide Deck titled, “Introduction to mCODE™ and the CodeX™ HL7® FHIR® Accelerator” available on the CodeX™ Confluence page.

HL7® FHIR® can address gaps in current REMS standards

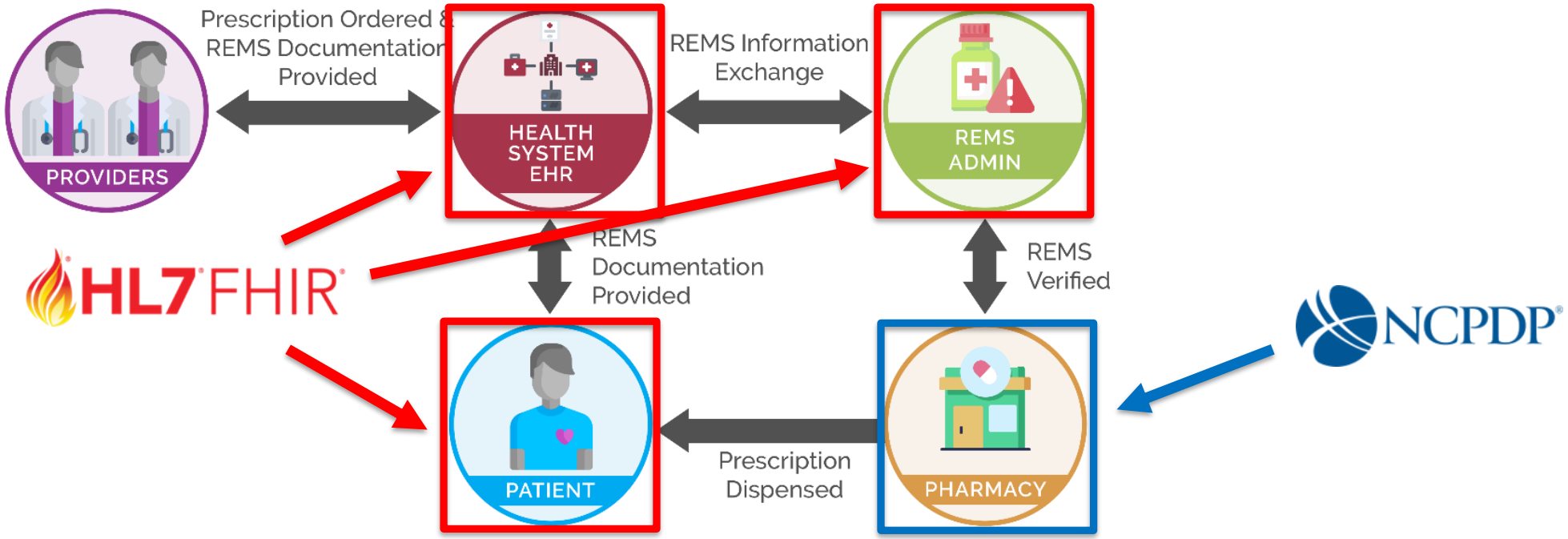
(Potential future state)



Blue boxes show the workflow addressed by current NCPDP Standards (Telecommunication, SCRIPT)

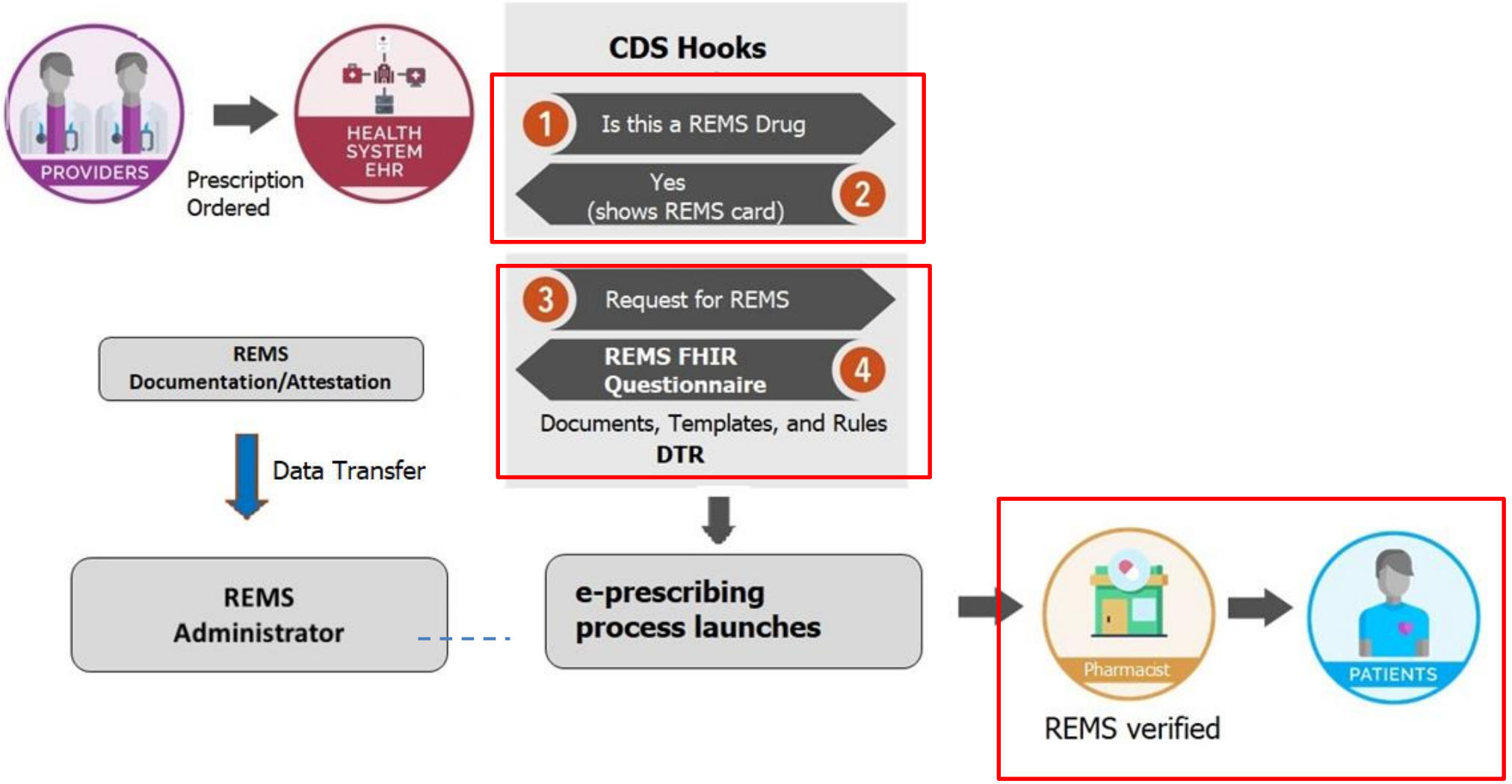
Slide adapted from MITRE's, "FDA CDER Risk Evaluation and Mitigation Strategies (REMS) Proof of Concept Landscape Analysis."

REMS Integration Proof-of-Concept/CodeX Use Case



https://confluence.hl7.org/display/COD/Risk+Evaluation+and+Mitigation+Strategies+-+REMS

REMS Workflow

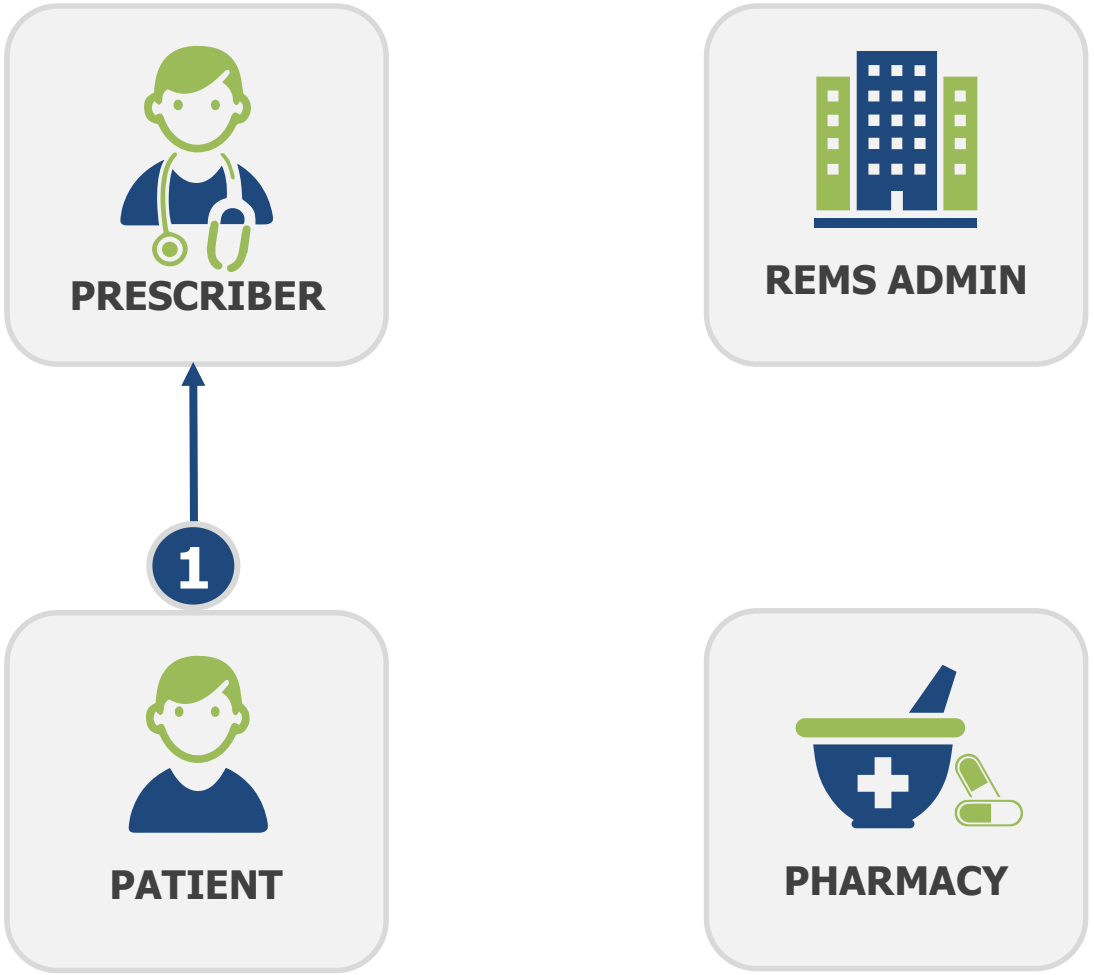


Slide adapted from MITRE's, "FDA CDER Risk Evaluation and Mitigation Strategies (REMS) Proof of Concept Landscape Analysis."

Prototype Workflow Overview

Slide adapted from CodeX™ REMS Integration Use Case Public Call Presentation, “CodeX™ REMS Integration Prototype,” by MITRE on February 14, 2023.

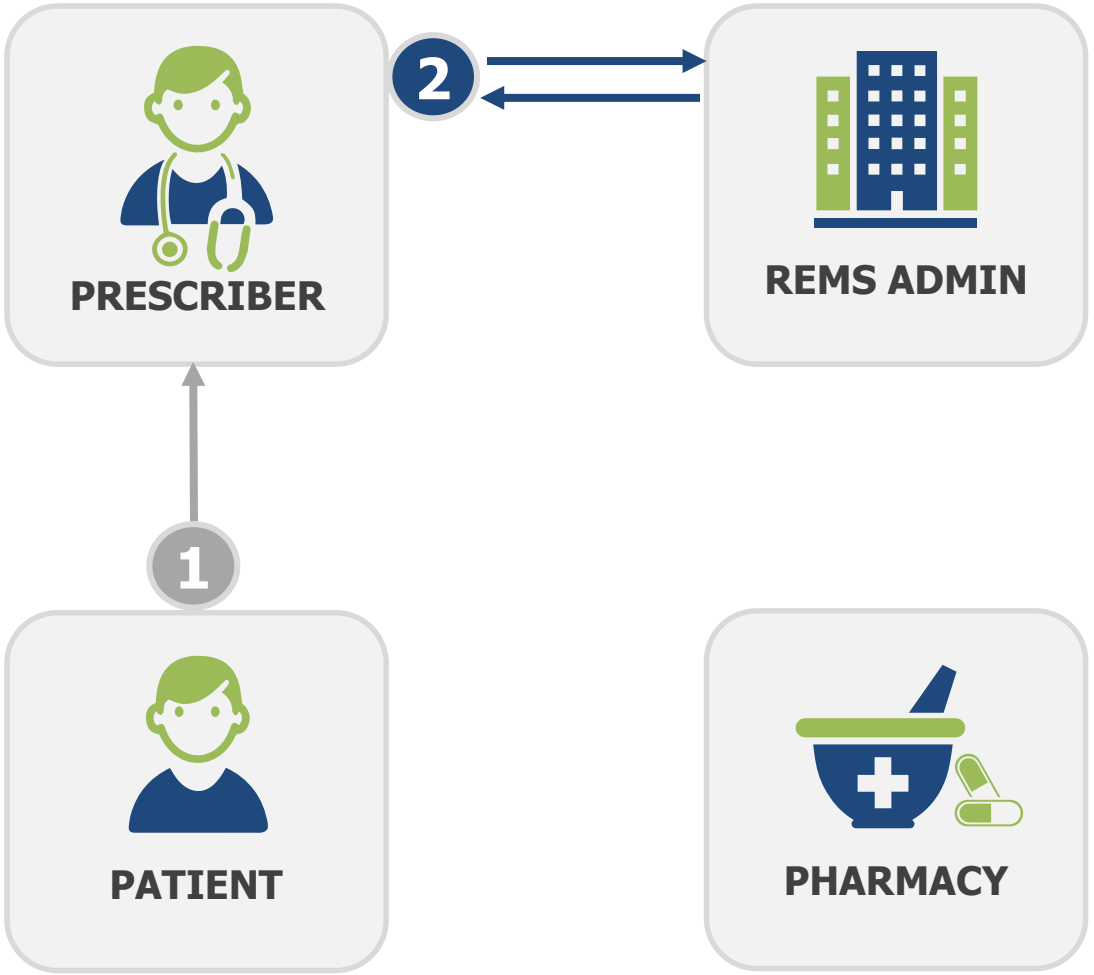
Prototype Workflow Overview



1. Patient Encounter

Slide adapted from CodeX™ REMS Integration Use Case Public Call Presentation, “CodeX™ REMS Integration Prototype,” by MITRE on February 14, 2023.

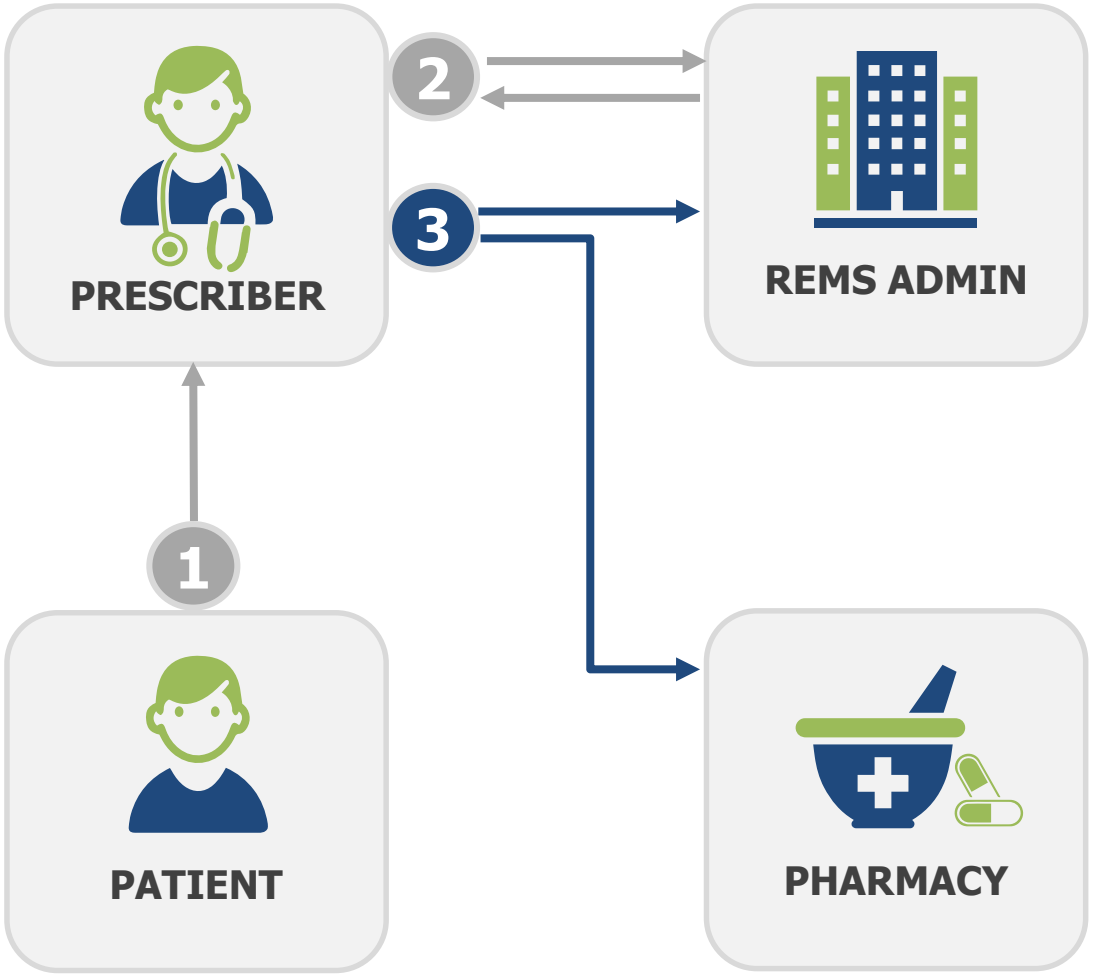
Prototype Workflow Overview



1. Patient Encounter
2. Obtain REMS documentation and forms

Slide adapted from CodeX™ REMS Integration Use Case Public Call Presentation, “CodeX™ REMS Integration Prototype,” by MITRE on February 14, 2023.

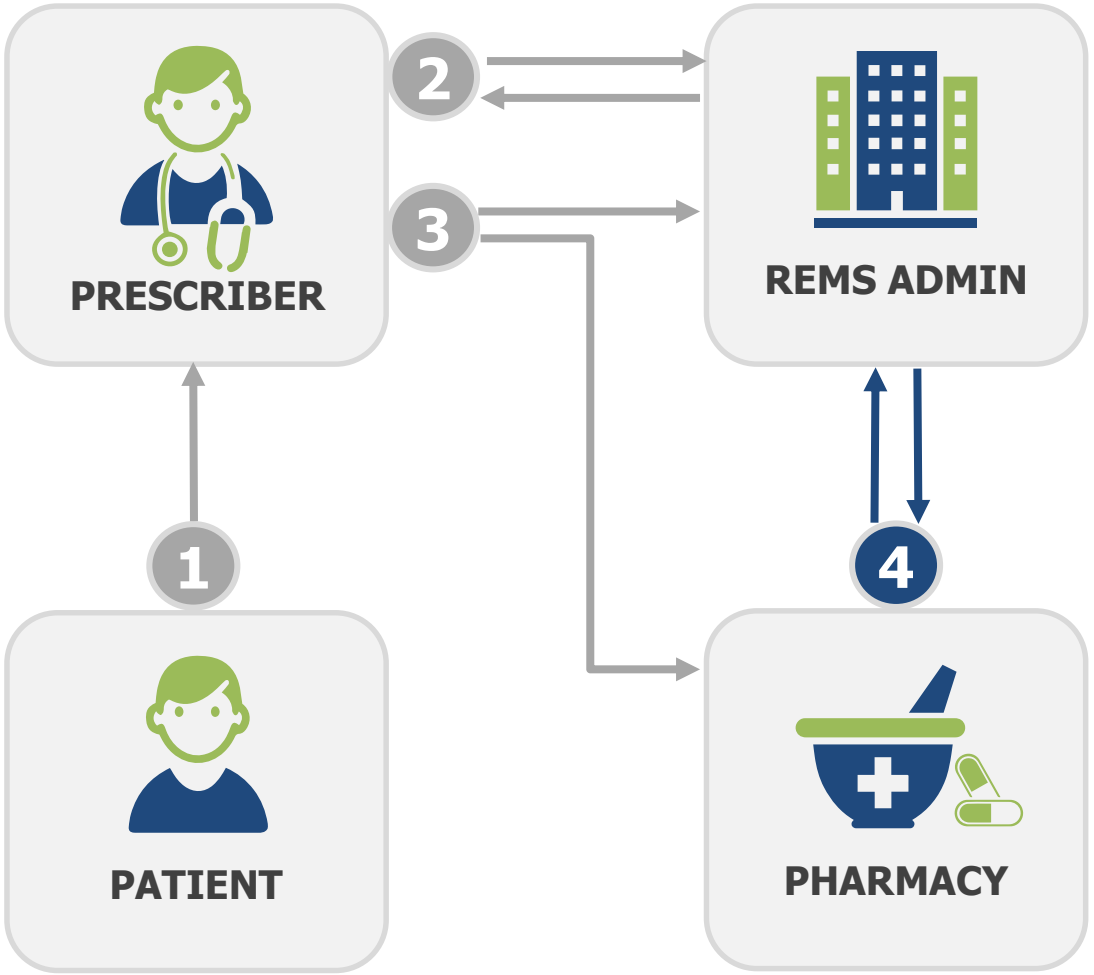
Prototype Workflow Overview



1. Patient Encounter
2. Obtain REMS documentation and forms
3. Submit prescription and REMS requirements

Slide adapted from CodeX™ REMS Integration Use Case Public Call Presentation, “CodeX™ REMS Integration Prototype,” by MITRE on February 14, 2023.

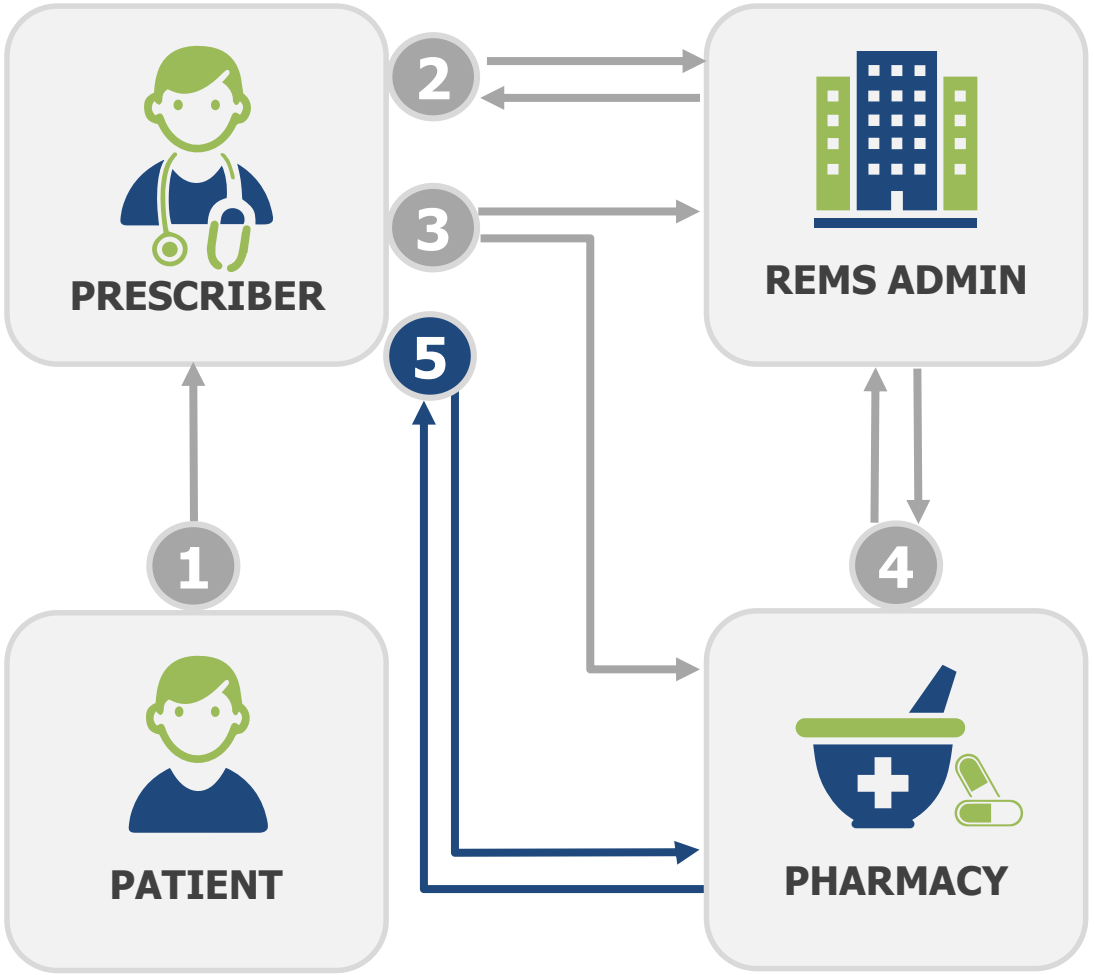
Prototype Workflow Overview



1. Patient Encounter
2. Obtain REMS documentation and forms
3. Submit prescription and REMS requirements
4. Pharmacy verifies REMS are met

Slide adapted from CodeX™ REMS Integration Use Case Public Call Presentation, "CodeX™ REMS Integration Prototype," by MITRE on February 14, 2023.

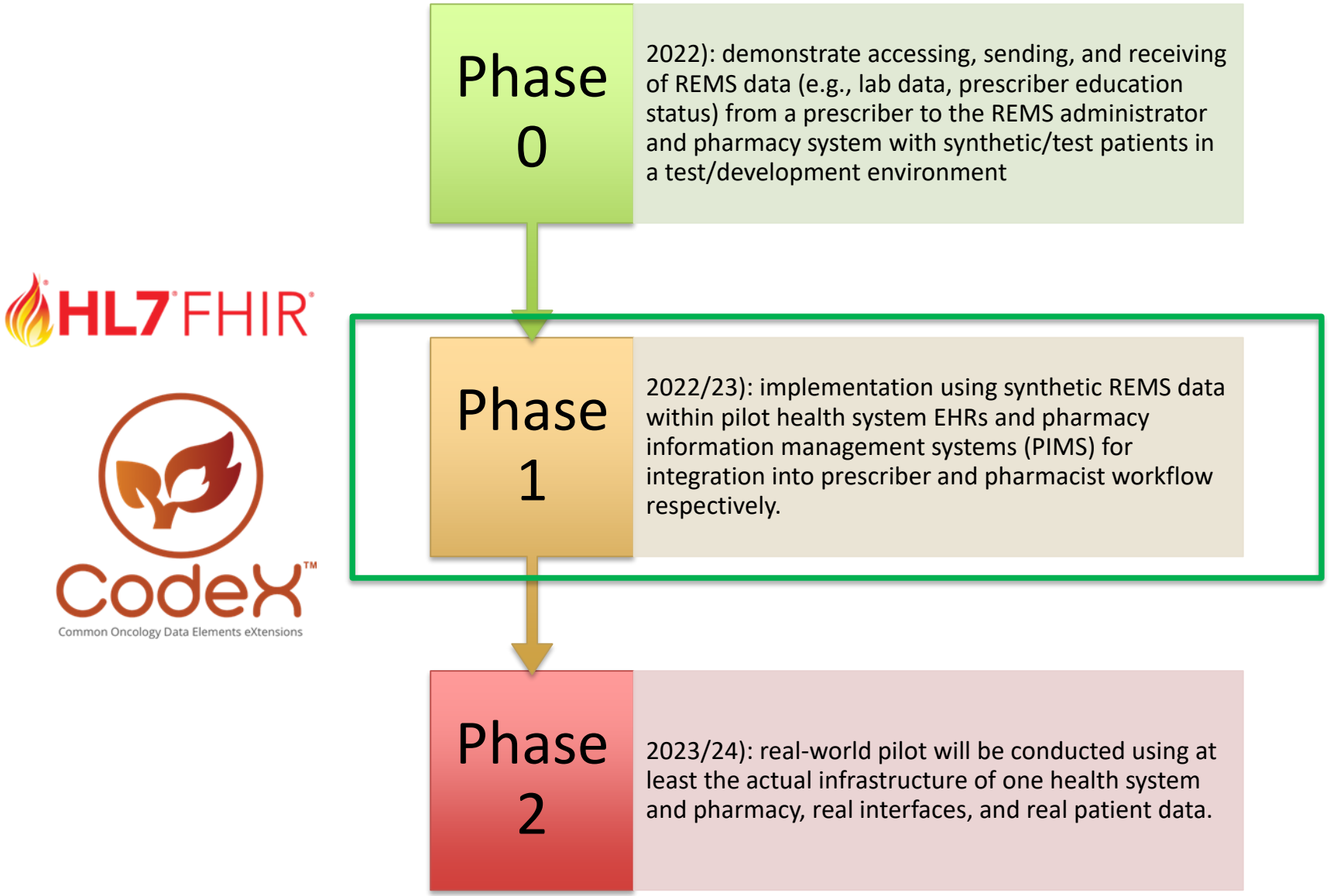
Prototype Workflow Overview



1. Patient Encounter
2. Obtain REMS documentation and forms
3. Submit prescription and REMS requirements
4. Pharmacy verifies REMS are met
5. Prescriber checks for status updates

Slide adapted from CodeX™ REMS Integration Use Case Public Call Presentation, "CodeX™ REMS Integration Prototype," by MITRE on February 14, 2023.

Planned CodeX™ REMS Integration Use Case Phases



Scalable, standards-based solution for REMS integration & optimization

* These phases do not include the development of a REMS data hub/platform or database for prescriber education and REMS data and information. This will need to be developed in the future.

REMS Integration Project Status

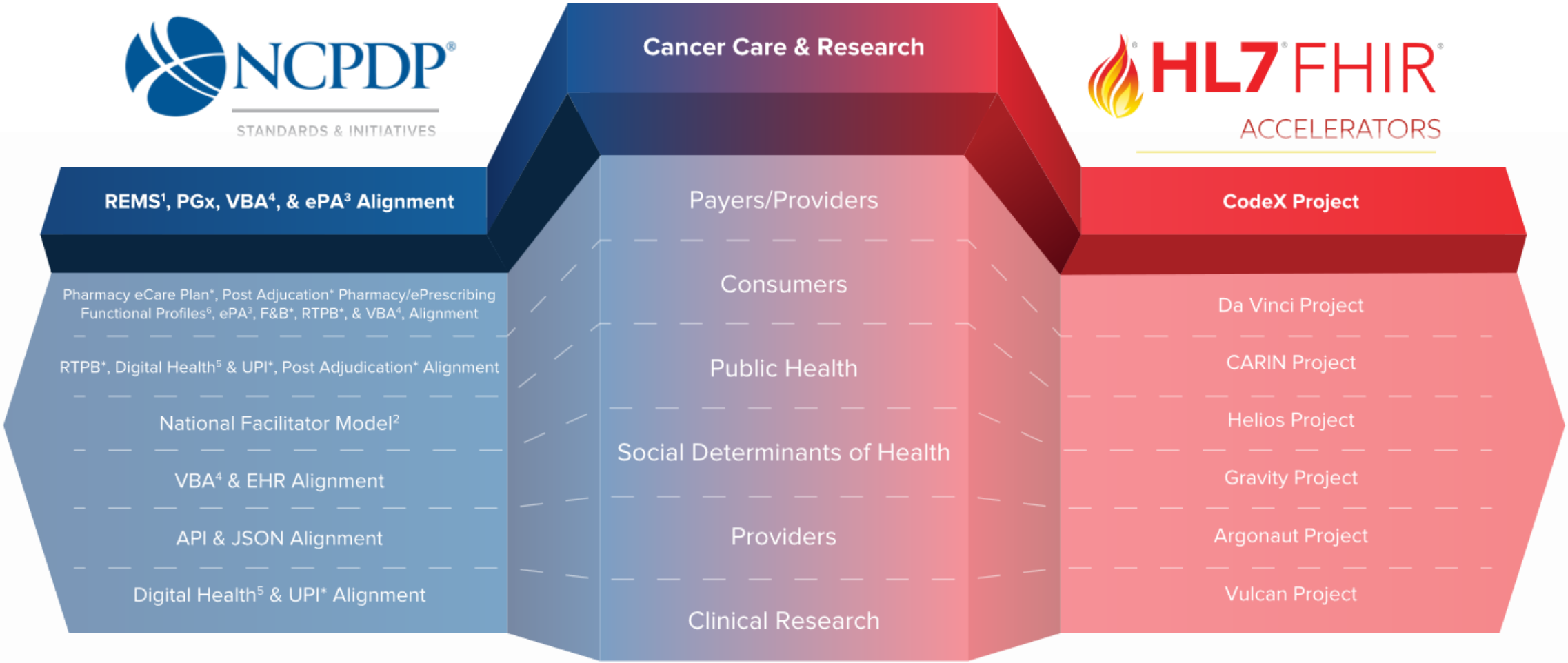
- **REMS use case:** 12th and most recent public use case call on 3/9; next public use case call 4/11; plan to start a pilot in the late Summer if commitments are achieved
  - Sign up for the upcoming 4/11 REMS Public Call under "Quick Links" at: https://confluence.hl7.org/display/COD/Risk+Evaluation+and+Mitigation+Strategies+-+REMS
- **Prototype development:** 8th iteration (REMSv0.8) released on 2/17
- **Public workshop on REMS Integration:** Held on 10/11/2022
  - Generally broad support for the REMS Integration prototype and approach
  - 300-400 participants for most of the webinar
  - Several stakeholders potentially interested in piloting

NCPDP® & HL7® FHIR® Cross-Pollination

Legend

* Existing NCPDP Standard
[1] Supported by Telecom & SCRIPT Standards
[2] Supported by SCRIPT, Telecom, & UPI Standards
[3] Supported by SCRIPT Standard
[4] Supported by SCRIPT, Telecom & Pharmacist eCare Plan Standards
[5] Supported by Billing Unit, Product Identifiers, SCRIPT, Telecom, F&B, RTPB & Benefit Integration Standards
[6] Separate standards developed jointly between NCPDP and HL7

FDA



Slide adapted from CodeX™ REMS Integration Use Case Public Call Presentation, "CodeX™ REMS Integration Use Case," by POCP on February 14, 2023.

REMS SPL Resources

- **REMS Document Technical Conformance Guide**
  - REMS Document Technical Conformance Guide at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/rems-document-technical-conformance-guide
- **REMS SPL submission requirements began Dec 28, 2022**
  - Providing Regulatory Submissions in Electronic Format -- Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-content-risk-evaluation-and-mitigation-strategies
- **FDA REMS SPL coding pages**
  - REMS SPL Sample at https://www.fda.gov/media/104656/download
  - https://www.fda.gov/industry/structured-product-labeling-resources/rems-approval
  - https://www.fda.gov/industry/structured-product-labeling-resources/rems-protocol
  - https://www.fda.gov/industry/structured-product-labeling-resources/rems-requirements
  - https://www.fda.gov/industry/structured-product-labeling-resources/rems-stakeholder
- **DailyMed SPL Indexing files**
  - REMS and REMS indexing files
    - https://dailymed-data.nlm.nih.gov/public-release-files/rems_document_and_rems_indexing_spl_files.zip

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Questions?


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