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

June 7, 2016

Common REMS Platform: Expert Workshop Use Case Overview

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June 7, 2016

Purpose of this Afternoon's session

Specifically…

- To help us review a use case for Prescriber Certification of REMS

More Generally…

- To pave the way for greater collaboration
- To help inform the design for future collaborations

Background: Prescriber Certification

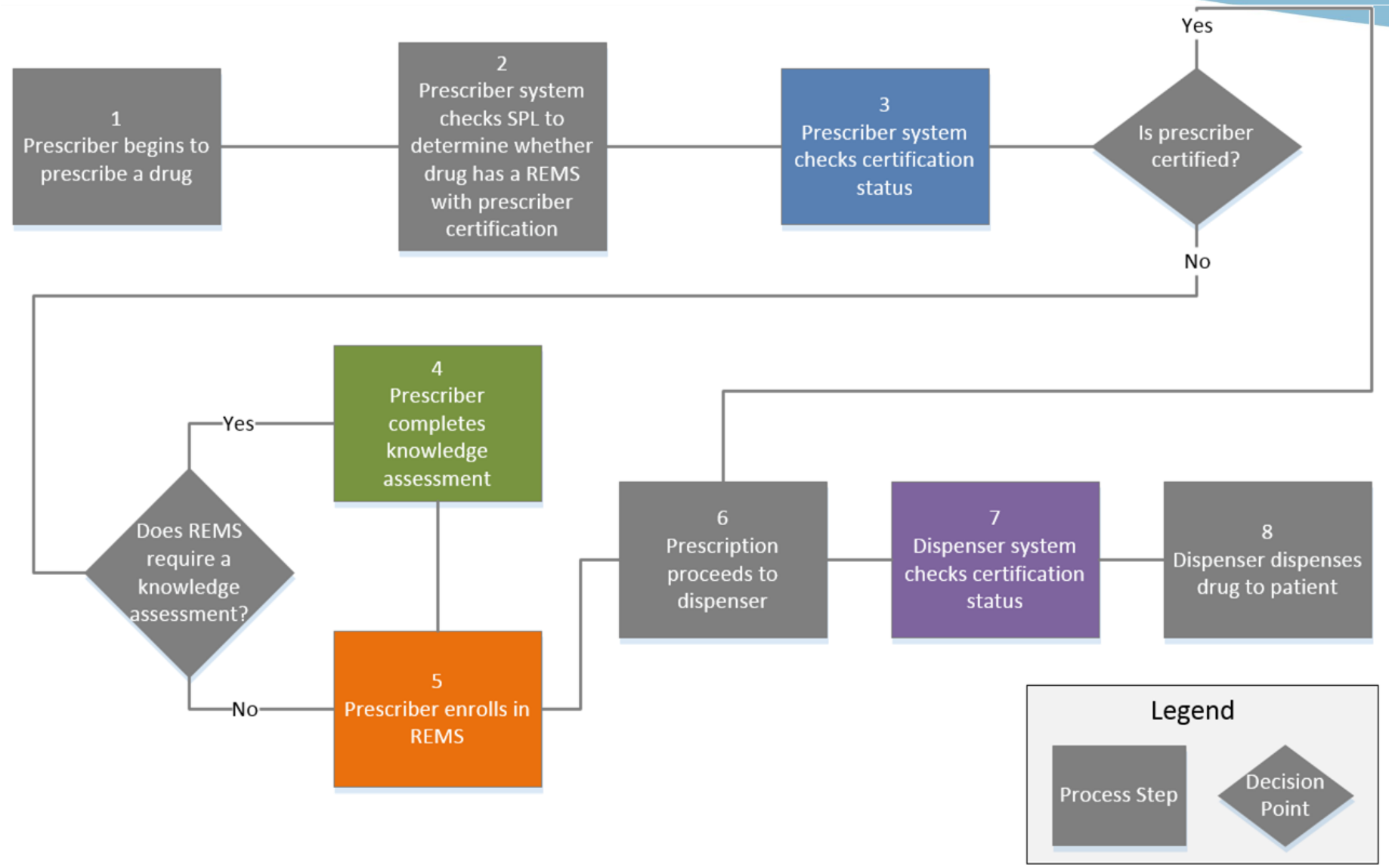
- In many REMS, sponsors must set up a system to ensure that only "certified" prescribers can prescribe a drug
- The process for prescribers to obtain this certification is referred to as "prescriber certification"
- Almost **all** REMS with Elements to Assure Safe Use require prescribers to be certified. There is little standardization of how this is done.

Steps for Prescriber Certification

To become certified, prescribers frequently must:

- Complete REMS training
  - ✓ Review REMS training materials
  - ✓ Complete a formal training course
  - ✓ Carry out a knowledge assessment
- Enroll in REMS
  - ✓ Acknowledge understanding of the drug's risks
  - ✓ Acknowledge or demonstrate ability to address risks
  - ✓ Agree to follow REMS requirements in the future
  - ✓ Complete the REMS enrollment form

Dispensers (i.e., pharmacists) often are called on to verify that these steps were carried out before dispensing


1
Prescriber begins to prescribe a drug
2
Prescriber system checks SPL to determine whether drug has a REMS with prescriber certification
3
Prescriber system checks certification status
Is prescriber certified?
Yes
No
4
Prescriber completes knowledge assessment
Yes
Does REMS require a knowledge assessment?
No
5
Prescriber enrolls in REMS
6
Prescription proceeds to dispenser
7
Dispenser system checks certification status
8
Dispenser dispenses drug to patient
Legend
Process Step
Decision Point

Prescriber Verification of Certification Status

Sub-process goals:

- Help the prescriber address any issues with certification before the prescription reaches the pharmacy
- Help prescriber confirm that they have met all certification requirements
- If not certified, inform the prescriber what they must do to become certified

Existing Standard:

- NCPDP SCRIPT

Dispenser Verification of Certification Status

Sub-process goals:

- Ensure that the drug isn't dispensed unless the prescriber was certified
- If prescriber is not certified, help the dispenser work with the prescriber to resolve the issue

Existing Standard:

- NCPDP Telecommunications

Prescriber Knowledge Assessment

Subprocess goals:

- Allow the prescriber to complete an electronic knowledge assessment
- Evaluate the knowledge assessment to ensure questions have been answered correctly
- Let the prescriber know if there were incorrect responses and proceed accordingly

Existing Standard:

- (none)

Prescriber Enrollment

Subprocess goals:

- Allow the prescriber to complete an electronic enrollment form
- Help streamline the enrollment process by auto-populating necessary fields

Existing Standard:

- None, but NCPDP SCRIPT addresses some of the requirements.

Plan for today: Schedule

- **1:50 PM Session IIIa Breakout: Data Elements**
- **2:45 PM Break**
- **3:00 PM Session IIIb Breakout: Process**
- **3:30 PM Presentation of Workgroup Findings and Group Discussion**
- **4:35 PM Closing Remarks**

Plan for today: Roles

- For much of the discussion you will be broken into subgroups. Your group is based on the location of the placards on your table.

- Each subgroup will have:
  - A Facilitator (Julia, Steve, or Adam A.)
  - An FDA Subject Matter Expert (Megan, Jason, or Gita)

- In addition, you may be joined by an HHS observer

- Steve Berman will be moderating the larger group discussion

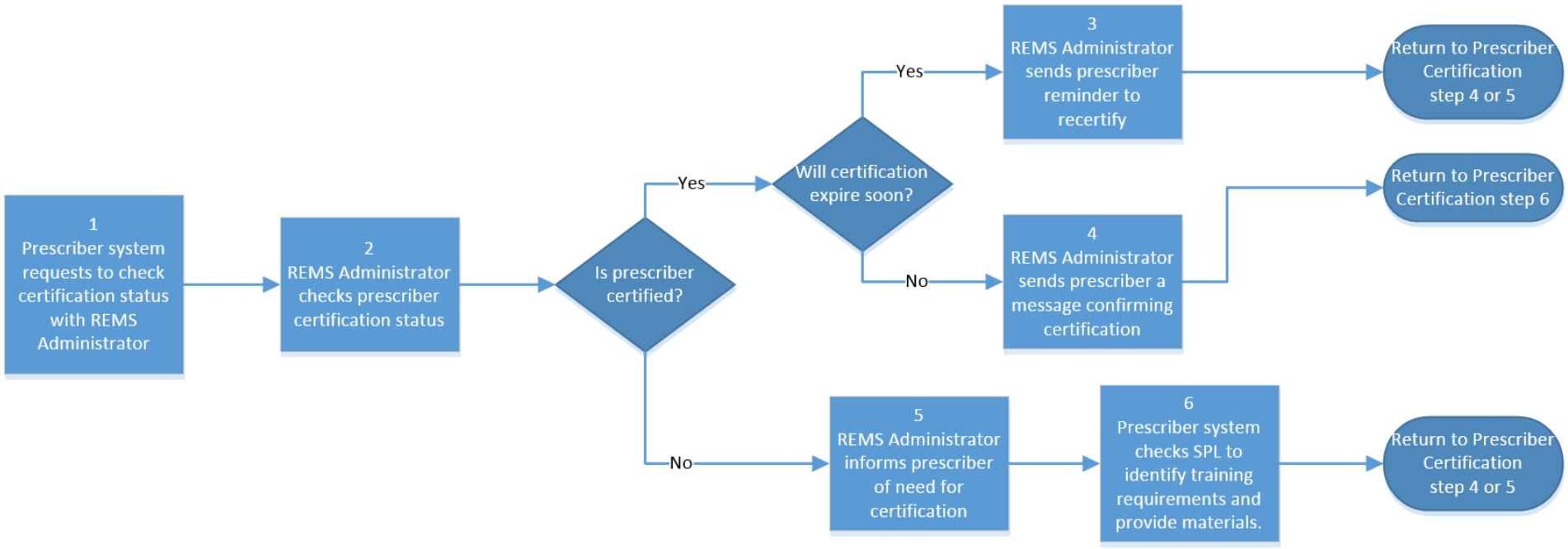
Questions: Session IIIa Breakout

- What data elements need to be exchanged to successfully carry out this scenario? And between whom?
- What is the purpose of each data element?
- Where does the data come from?

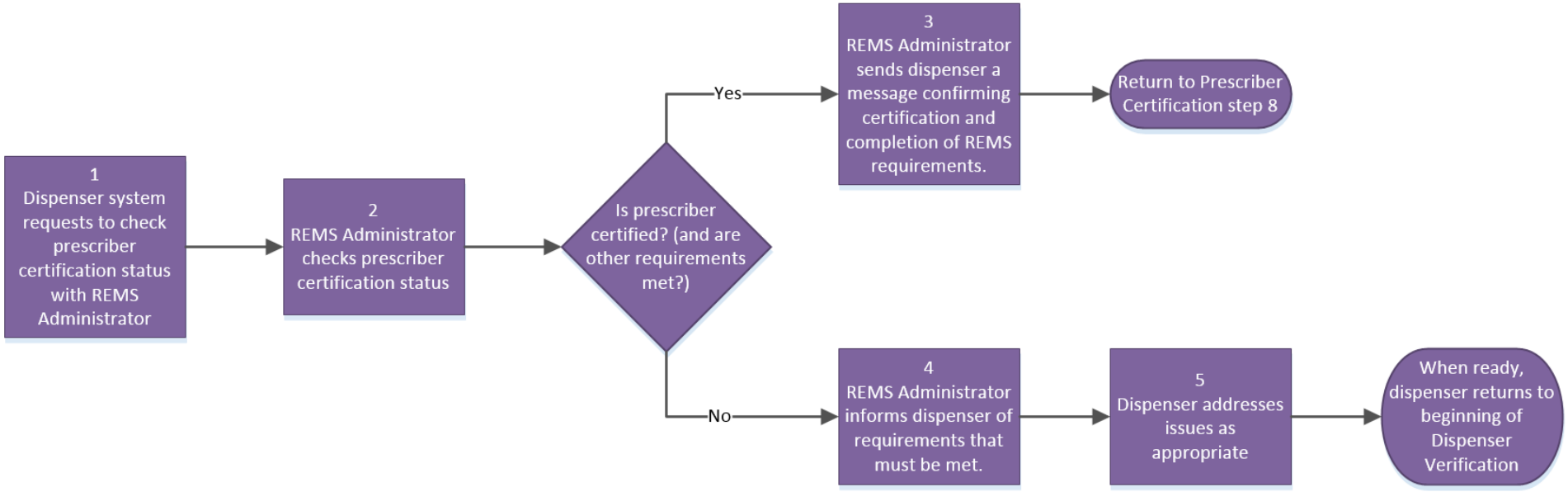
Questions: Session IIIb Breakout

- How can we ensure that these processes:
  - Allow for the exchange of the necessary data elements,
  - Assure timely patient access to REMS drugs,
  - Are compatible with a wide range of healthcare settings, and
  - Support transfer of information across different settings of care?
- How might REMS Structured Product Labeling (SPL) support these processes?
- What considerations should be kept in mind when developing standards based on these processes?

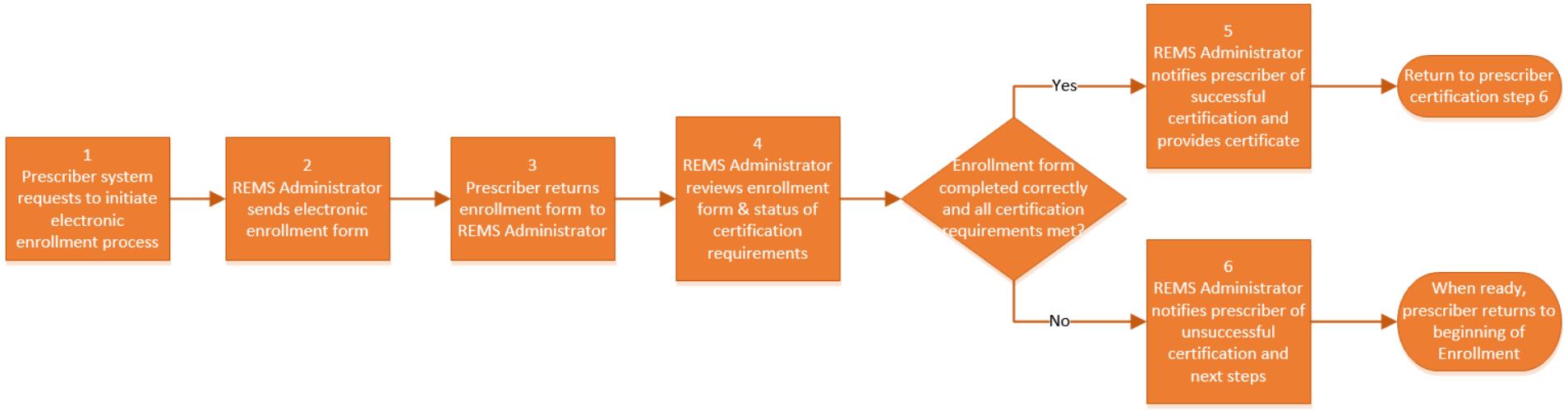
Prescriber Verification of Certification Status



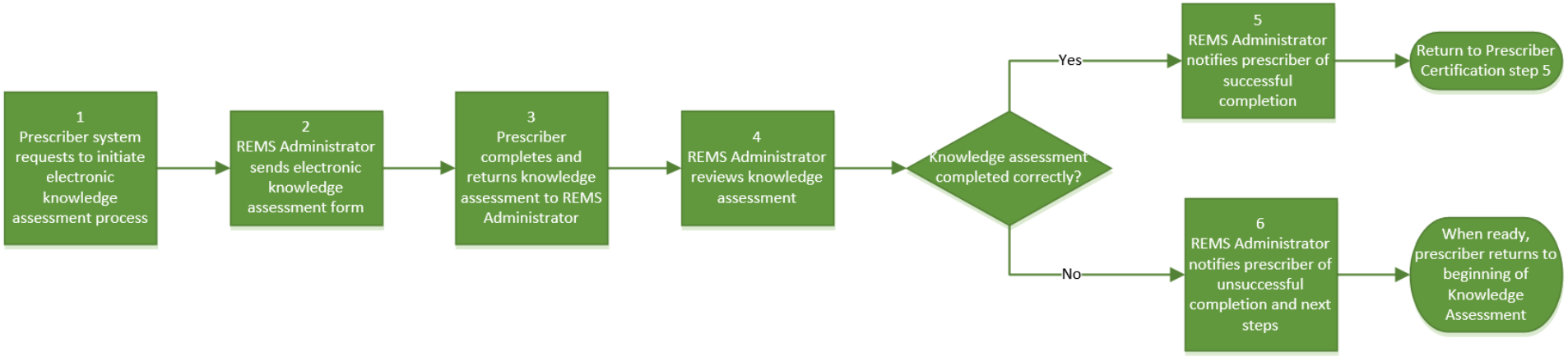
Dispenser Verification of Certification Status



Prescriber Enrollment



Prescriber Knowledge Assessment



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