

Building a Common REMS Platform: Use Case Guide for Prescriber Certification

Thank you for participating in our first Common REMS Platform Workshop! During this workshop, FDA will be presenting its proposed use case for prescriber certification under REMS. The purpose of the workshop is to help review the use case (described in greater detail below) to ensure that the processes outlined:

- Allow for the exchange of the necessary data,
- 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

It is FDA's hope that the work done at this workshop will help pave the way for the development of platform standards to support the prescriber certification process. It is also hoped that this will be the first of many collaborative sessions to help develop platform standards, and that our experience at this session will help guide the design of future collaborations.

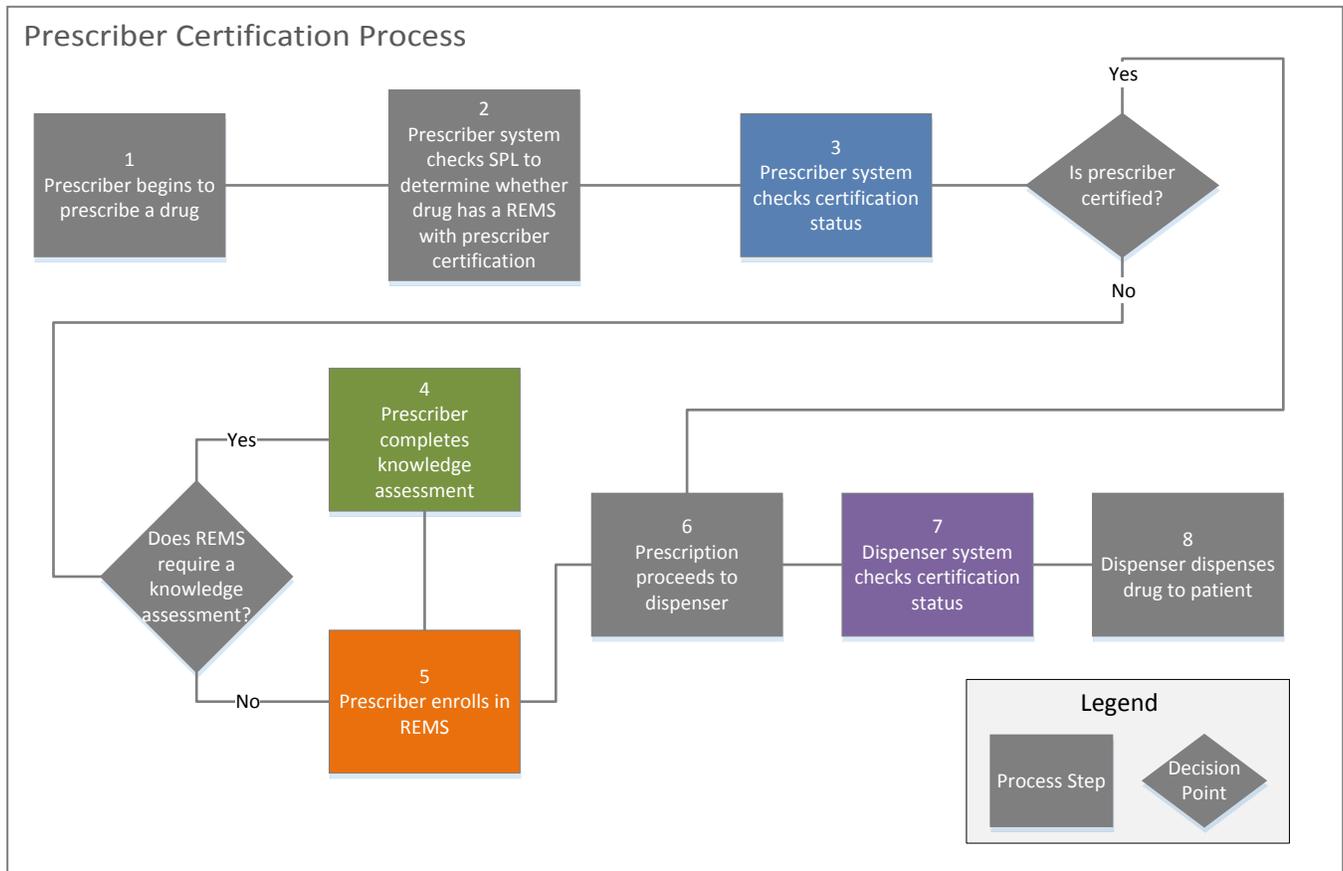
Background: Prescriber Certification

In many REMS, healthcare providers must complete certain REMS requirements in order to be able to prescribe, dispense, or order a drug. Once a healthcare provider or setting has met these requirements, they are referred to as "certified." For healthcare providers who prescribe the drug, the process for obtaining this certification is referred to as "prescriber certification."

In order to become certified, prescribers must meet a number of requirements. Nearly all approved REMS require that healthcare providers enroll in the REMS by providing basic demographic information to the REMS program (typically through the use of an enrollment form). Those that do require healthcare providers to enroll also require them to acknowledge that they understand the drug's risks and how to use the drug safely, and agree to follow certain REMS requirements when treating patients with the drug. In addition, REMS with prescriber certification may require that providers acknowledge or demonstrate (e.g., via a knowledge assessment) that they possess certain experience or abilities (e.g., the ability to diagnose or treat certain adverse events), have completed REMS-required training, or that they have systems in place to ensure and document the completion of REMS requirements. Dispensers often are called on to verify that a prescriber is certified prior to dispensing a drug to a patient.

Use Case

The following diagram shows the proposed overall prescriber certification process to be discussed at the workshop:



Certain boxes are color-coded to represent specific subprocesses that the group will explore in greater detail. Each subprocess represents an exchange of information between prescribers or dispensers and REMS Administrators.

The subprocesses include:

1. Prescriber Verification of Certification Status (in **blue**)
2. Dispenser Verification of Certification Status (in **purple**)
3. Prescriber Knowledge Assessment (in **green**)
4. Prescriber Enrollment (in **orange**)

Note that each subprocess may be carried out either in sequence as part of the overall certification process or separately whenever a prescriber or dispenser wishes to exchange the relevant information with the REMS administrator. For example, the certification process calls for prescribers to verify their certification status at the time of prescribing, but permits them to do so at other times as well.

Participants will be dividing into three subgroups to discuss each of these subprocesses: The first group will discuss both Prescriber Verification of Certification Status and Dispenser Verification of Certification Status; the second and third group will discuss Prescriber Knowledge Assessment and Prescriber Enrollment, respectively. While each subgroup will focus on its assigned subprocess, in the final portion of the workshop all attendees will have the opportunity to comment on any subprocess as well as the prescriber certification process as a whole.

To help facilitate the discussion of these subprocesses, FDA has created handouts that describe, for each subprocess, data that may be exchanged and the process by which that exchange may be carried out. During the workshop FDA will be inviting comments and suggestions on each of these documents. FDA suggests that participants review these handouts in advance of the meeting to help ensure a productive discussion.

Prescriber Verification of Certification Status – Data Elements

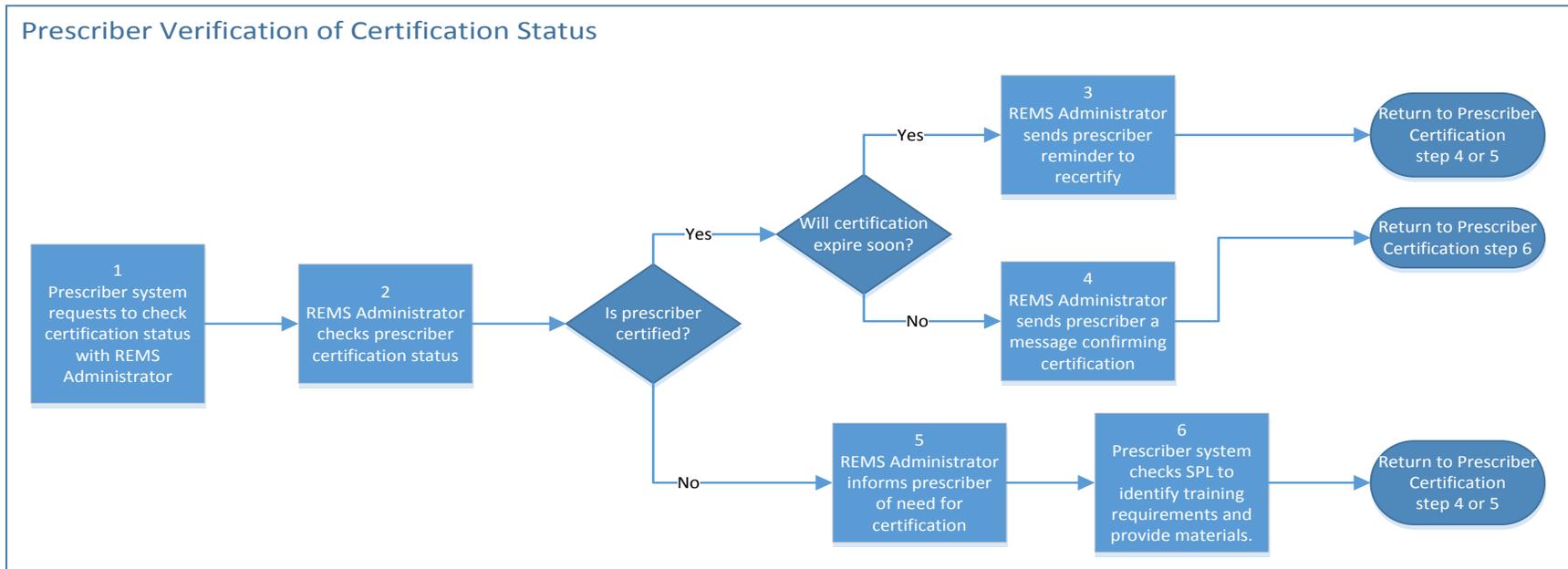
Data received by the prescriber

Element	Description / Purpose	Source
REMS Certification Requirements	Detailed list of REMS requirements prescriber must meet in order to be certified	REMS SPL (via EHR's drug database)
Certification Materials	Copies and/or links to materials prescribers may need as part of the certification process (e.g., training materials)	REMS SPL (via EHR's drug database)
Requirement completion status	Yes/no element that verifies whether training, knowledge assessment, and other requirements have been met.	REMS Administrator database
Requirements to be met	Text description of requirements that must still be met if the requirements are not complete	REMS Administrator database

Data received by the REMS Administrator

Element	Description / Purpose	Source
Prescriber First Name	Prescriber identifier	Prescriber (auto-populated by their EHR)
Prescriber Last Name	Prescriber identifier	Prescriber (auto-populated by their EHR)
Prescriber NPI#	Prescriber identifier	Prescriber (auto-populated by their EHR)
Prescriber DEA#	Prescriber identifier	Prescriber (auto-populated by their EHR)
Prescriber Phone	Contact information	Prescriber (auto-populated by their EHR)
Prescriber Email	Contact information	Prescriber (auto-populated by their EHR)

Prescriber Verification of Certification Status – Process



1. The prescriber system asks the REMS administrator to check the prescriber's certification status by providing identifying information for the prescriber and any authentication credentials required by the REMS Administrator. When implemented in an e-prescribing system, this step may be carried out automatically when the prescriber chooses to prescribe a REMS drug.
2. The REMS administrator checks the prescriber's certification status.
 - If the prescriber is certified and certification *will* expire soon, go to step 3.
 - If the prescriber is certified and certification will *not* expire soon, go to step 4.
 - If the prescriber is not certified, go to step 5.
3. If the prescriber is certified and certification *will* expire soon, the REMS Administrator sends the prescriber a reminder to re-certify. Go to step 5. When implemented in an e-prescribing system, prescribing may proceed after this step.
4. If the prescriber is certified and certification will *not* expire soon the prescriber receives a message noting that they are certified.
5. If the prescriber is not certified, the REMS Administrator informs the prescriber of the need for certification. When implemented in an e-prescribing system, prescribing should not proceed after this step.
6. The prescriber system checks the REMS SPL to determine the REMS' training requirements so that prescribers can complete the training and proceed to the knowledge assessment, if needed.

Dispenser Verification of Certification Status – Data Elements

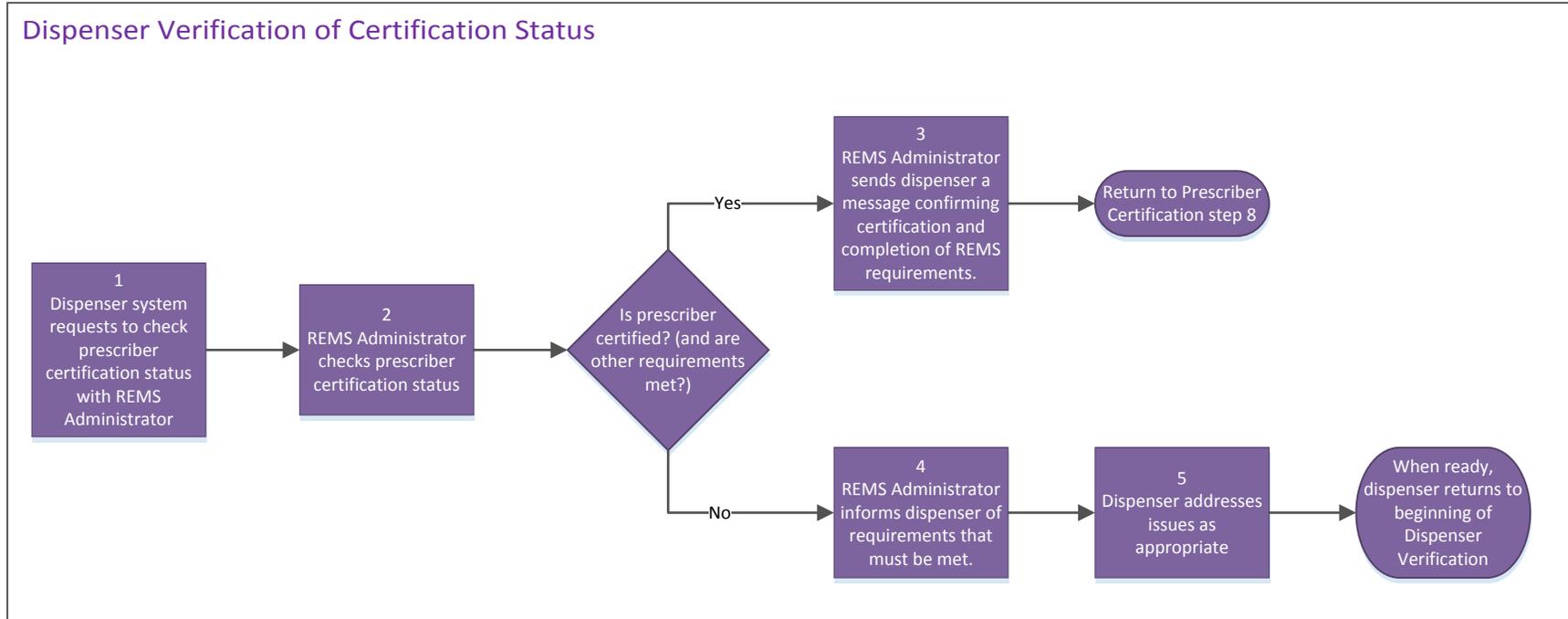
Data received by the dispenser

Element	Description / Purpose	Source
Requirement completion status	Yes/no element that verifies whether training, knowledge assessment, and other requirements have been met.	REMS Administrator database
Requirements to be met	Text description of requirements that must still be met if the requirements are not complete	REMS Administrator database

Data received by the REMS Administrator

Element	Description / Purpose	Source
Prescriber First Name	Prescriber identifier	Dispenser (received from prescriber)
Prescriber Last Name	Prescriber identifier	Dispenser (received from prescriber)
Prescriber NPI#	Prescriber identifier	Dispenser (received from prescriber)
Prescriber DEA#	Prescriber identifier	Dispenser (received from prescriber)
Prescriber Phone	Contact information	Dispenser (received from prescriber)
Prescriber Email	Contact information	Dispenser (received from prescriber)
Dispensing Pharmacy NCPDP ID	Identifies dispenser (for retail pharmacies)	Dispenser (auto-populated by pharmacy system)
Dispenser NPI#	Identifies dispenser	Dispenser (auto-populated by EMR / pharmacy system)

Dispenser Verification of Certification Status – Process



1. The dispenser system asks the REMS administrator to check the prescriber's certification status by providing identifying information for the prescriber and any authentication credentials required by the REMS Administrator. When implemented in a pharmacy system, this step may be carried out automatically when the dispenser chooses to dispense a REMS drug.
2. The REMS administrator checks the prescriber's certification status.
 - If the prescriber is certified, go to step 3.
 - If the prescriber is not certified, go to step 4.
3. If the prescriber is certified the dispenser receives a message noting that they are certified.
4. If the prescriber is not certified, the REMS Administrator informs the dispenser of the need for the prescriber to be certified. When implemented in a pharmacy system, dispensing should not proceed after this step.
5. As appropriate, the dispenser may contact the prescriber and work with them to ensure that REMS requirements are met.

Prescriber Knowledge Assessment – Data Elements

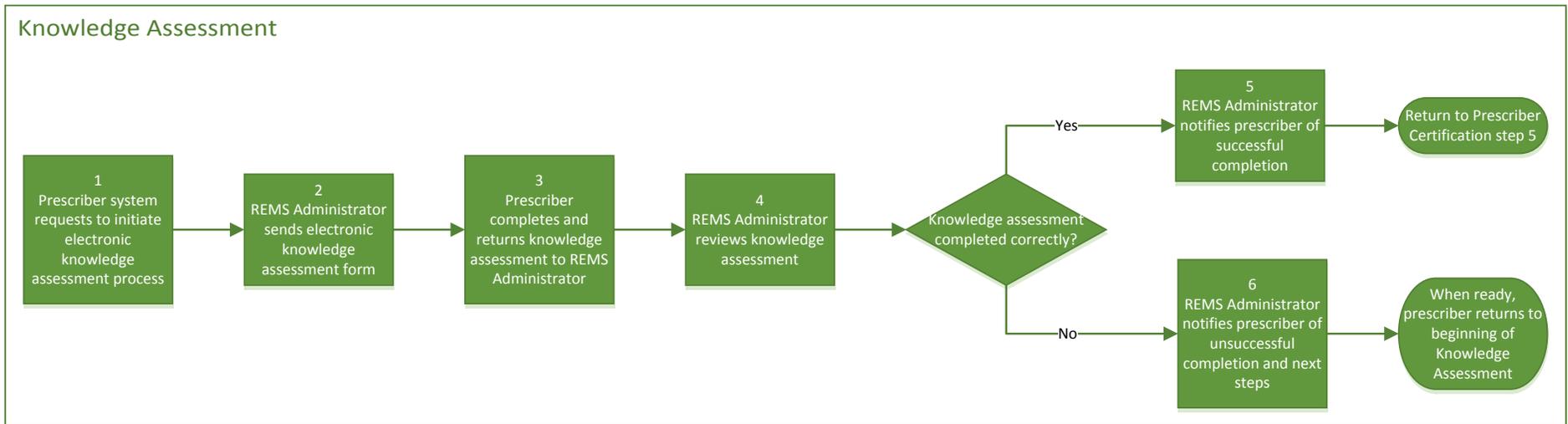
Data needed by the prescriber

Element	Description / Purpose	Source
Knowledge assessment questions	Questions that are part of the knowledge assessment	REMS Administrator
Answer choices	Possible answer choices for each question, as well as instructions	REMS Administrator
Instructions	Instructions for the knowledge assessment as a whole or for individual questions (e.g. whether prescribers should select only one answer or may select multiple answers for each question).	REMS Administrator

Data needed by the REMS Administrator

Element	Description / Purpose	Source
Prescriber First Name	Identifies prescriber	Auto-populated by prescriber EHR
Prescriber Last Name	Identifies prescriber	Auto-populated by prescriber EHR
Prescriber NPI#	Identifies prescriber	Auto-populated by prescriber EHR
Prescriber DEA#	Identifies prescriber	Auto-populated by prescriber EHR
Prescriber Phone	Contact information	Auto-populated by prescriber EHR
Prescriber Email	Contact information	Auto-populated by prescriber EHR
Knowledge Assessment Answers	<p>Allow the prescriber to submit an answer to a multiple choice question.</p> <p>Flexibility is needed both in terms of:</p> <ul style="list-style-type: none"> • Total number of questions (and corresponding answers submitted) • Total number of answer options per question (e.g. a True/False question might only have two, whereas others could have 6+ options) <p>For each question, one or more answers may be submitted</p>	Manually entered by the prescriber

Prescriber Knowledge Assessment – Process



1. The prescriber sends an electronic request through the prescriber system to the REMS Administrator to initiate the knowledge assessment process. (note: this electronic request does not need to be associated with a specific prescription).
2. The REMS administrator sends the prescriber an electronic knowledge assessment (i.e., a list of the fields that must be filled out to complete the electronic knowledge assessment).
3. The prescriber fills out the electronic knowledge assessment and sends the completed knowledge assessment to the REMS Administrator. Certain demographic fields (i.e., prescriber name, NPI) may be pre-populated by the prescriber system.
4. Upon receipt of the completed knowledge assessment, the REMS administrator determines whether the prescriber answered a sufficient number of questions correctly to “pass” the knowledge assessment.
 - If the knowledge assessment was completed successfully, go to step 5
 - If the knowledge assessment was not completed successfully, go to step 6
5. If the prescriber has passed the knowledge assessment, the REMS administrator notifies the prescriber that they have successfully done so. Proceed to “Enrollment” below.
6. If the prescriber has not passed the knowledge assessment, the REMS administrator notifies the prescriber. If the prescriber got any answers wrong, the administrator may provide the correct answers and their explanations in an accompanying text field. The prescriber system may prompt the prescriber to return to step 1 when the prescriber is ready to take the knowledge assessment again.

Prescriber Enrollment – Data Elements

Data received by the prescriber

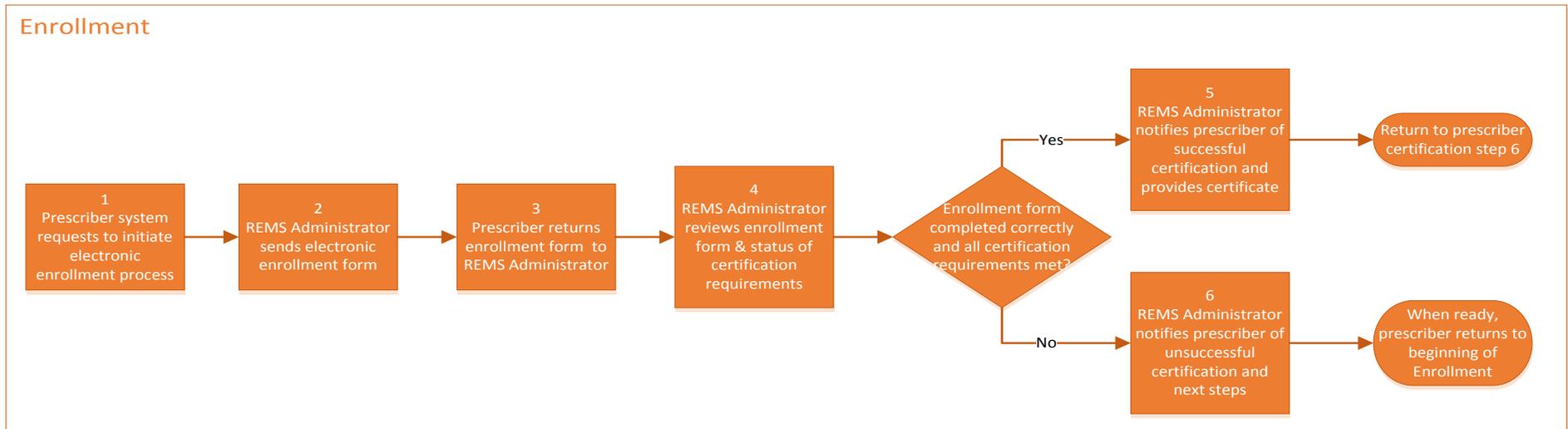
Element	Description / Purpose	Source
List of enrollment fields	List of fields that prescriber must complete in the enrollment form, as well as the type of information that each field should contain (see below for more details)	REMS Administrator
Enrollment errors	Description of errors that may have occurred when the prescriber attempted to enroll	REMS Administrator

Data received by the REMS Administrator

Element	Description / Purpose	Source
Signature	Validates prescriber agreement	
Date	Validates prescriber agreement	
First Name	Prescriber Identifier	Auto-populated by prescriber EHR
Middle Name/ Initial	Prescriber Identifier	Auto-populated by prescriber EHR
Last Name	Prescriber Identifier	Auto-populated by prescriber EHR
Degree		
Specialty		
NPI#	Prescriber Identifier	Auto-populated by prescriber EHR
DEA#	Prescriber Identifier	Auto-populated by prescriber EHR
State license #	Prescriber Identifier	Auto-populated by prescriber EHR
State of [license] Issue	Prescriber Identifier	Auto-populated by prescriber EHR
Practice Name	Identifies practice	Auto-populated by prescriber EHR
Practice Setting	Identifies practice	Auto-populated by prescriber EHR
Address	Contact information	Auto-populated by prescriber EHR
Address 2	Contact information	Auto-populated by prescriber EHR
City	Contact information	Auto-populated by prescriber EHR
State	Contact information	Auto-populated by prescriber EHR
Zip	Contact information	Auto-populated by prescriber EHR
Phone	Contact information	Auto-populated by prescriber EHR

Fax	Contact information	Auto-populated by prescriber EHR
Email	Contact information	Auto-populated by prescriber EHR
Preferred Method of Contact	Prescriber preference	
Office Contact First Name	Alternate contact information	
Office Contact Last Name	Alternate contact information	
Office Contact Email	Alternate contact information	
Office Contact Phone	Alternate contact information	
Office Contact Fax	Alternate contact information	
Alternate/ Mobile Phone #	3 rd line contact information	
Confirm Email		Auto-populated by prescriber EHR
Additional Practice Location	Contact information	
Affiliated Hospital	Contact information	
Delegates	Identifies delegate	
Tax ID#		
Acknowledgment Field(s)	Yes/No (i.e., checkbox) field indicating whether prescriber acknowledges specific requirements	

Prescriber Enrollment – Process



1. The prescriber sends an electronic request through the prescriber system to the REMS Administrator to initiate the enrollment process. (note: this electronic request does not need to be associated with a specific prescription).
2. The REMS Administrator sends the prescriber the electronic enrollment form (i.e., a list of the fields that must be filled out to complete the electronic enrollment process).
3. The prescriber fills out the electronic enrollment form and sends that information to the REMS Administrator via the prescriber's system. Some fields may be pre-populated by the prescriber system.
4. Upon receipt of a complete electronic enrollment form the REMS administrator checks whether the prescriber has successfully completed the enrollment form and met all requirements for certification.
 - If the certification was successful, go to step 5
 - If the certification was not successful, go to step 6
5. If certification was successful, the message acknowledges that the prescriber has been certified, and provides a unique "REMS enrollment certificate" that identifies the REMS and the fact that the prescriber was certified under the REMS. If the prescriber's certification has an expiration date, this date is included in the certificate as well. This certificate can later be used to verify that the prescriber is authorized to prescribe that drug.
6. If the certification is not successful, the REMS Administrator sends an error message that explains why (e.g., whether information was missing or certain REMS requirements were not met). If appropriate, the message may explain next steps the prescriber should take to resolve the issue.