January 17, 2018

Dockets Management Staff (HFA–305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA–2013–N–0502 for ‘‘REMS Platform Standards Initiative: Needs Assessment; Request for Comments.”

To whom it may concern:

NCPDP is a not-for-profit ANSI-Accredited Standards Development Organization (SDO) consisting of more than 1,400 members who represent drug manufacturers, chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, pharmaceutical claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies, professional societies, and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry. NCPDP provides a forum wherein our diverse membership can develop solutions, including ANSI-accredited standards, and guidance for promoting information exchanges related to medications, supplies, and services within the healthcare system.

NCPDP appreciates this opportunity to provide comments and respond to the following questions outlined in Docket # FDA–2013–N–0502, “*REMS Platform Standards Initiative: Needs Assessment; Request for Comments”*.

*(1) Does this needs assessment cover all of the REMS activities for which standards development would be beneficial?*
**NCPDP Comment:** NCPDP believes this needs assessments covers all the necessary REMS activities for which standards development would be beneficial at this time.

*(2) Which REMS activities should be given highest priority for standards development?*
**NCPDP Comment:** NCPDP recommends the following be given the highest priority for standards development.

- Use of the current REMS transactions in the NCPDP SCRIPT Standard v2017071 specifically for ETASU related activities
- Identify barriers for adoption of the NCPDP SCRIPT REMS transaction (see question 3)
- Standardization of enrollment may require the creation of a possible new transaction by NCPDP for enrollment of pharmacies, pharmacists, prescribers and patients

*(3) What standards already exist that could be used to address the needs and facilitate the REMS activities described in the needs assessment?*
**NCPDP Comment:** NCPDP has developed a series of electronic transactions for the exchange of information between a healthcare provider and a REMS administrator.

- NCPDP created the following REMS transactions. More information about these transactions is available in the NCPDP SCRIPT Implementation Guide v2017071.
    - **REMSInitiationRequest** - This transaction is a request to the REMS administrator for the information required to submit a REMSRequest. It is a request for the information required to submit a REMS request for a specified patient and drug.
    - **REMSInitiationResponse** - This transaction is a response from the REMS administrator with the information required to submit a REMSRequest. It is a response with the information required to submit a REMS request for a specified patient and drug.
    - **REMSRequest** - This transaction is a request to the REMS administrator with information (answers to question set; clinical documents) to make a REMS determination (approved, denied, pended, etc.). The message can be used for more complex ETASU activities
    - **REMSResponse** - This transaction is a response from the REMS administrator to a REMSRequest.

During the review of the *REMS Platform Standards Initiative: Needs Assessment* document, NCPDP identified efficiency gaps and possible enhancements to the current REMS transactions that may improve workflow.

| Gap Identified | Section | Text | Solution |
|---|---|---|---|
| Acknowledgement | 4.1.1 Complete REMS Acknowledgments and Agreements for Certification | Acknowledgement checks (i.e. Checkboxes or yes/no responses to indicate that the health care provider has read, reviewed and confirmed each acknowledgment and agreement. | Possible new transaction for confirmation/certification and notifications. |
| Acknowledgement | 4.2.4 Enroll Patient in the REMS | Acknowledgment of successful enrollment | Possible new transaction for confirmation/certification and notifications. |
| Confirmation | 4.3.1 Monitor Patient's Condition and Status | Confirmation of receipt of information | Possible new transaction for confirmation/certification and notifications. |
| Confirmation | 4.2.1Complete Prescriber Acknowledgments and Agreements for Initiation of Treatment | Confirmation of receipt of the prescriber's attestations | Possible new transaction for confirmation/certification and notifications. |
| Confirmation | 4.2.1Complete Prescriber Acknowledgments and Agreements for Initiation of Treatment | Checkboxes or yes/no responses to indicate that the prescriber has read and confirmed each attestation statement | Possible new transaction for confirmation/certification and notifications. |
| Confirmation | 4.2.1Complete Prescriber Acknowledgments and Agreements for Initiation of Treatment | Confirmation (e.g., a digital signature) that the prescriber has read and understood all of the attestation statements | Possible new transaction for confirmation/certification and notifications.<br>Review current digital signature requirement in the REMS transaction and make modifications if necessary. |
| Confirmation | 4.2.2Complete Patient Acknowledgments and Agreements for Initiation of | Confirmation of receipt of acknowledgments and agreements | Possible new transaction for confirmation/certification and notifications. |

| Gap Identified | Section | Text | Solution |
|---|---|---|---|
| | Treatment | | |
| Confirmation | 4.2.2Complete Patient Acknowledgments and Agreements for Initiation of Treatment | Checkboxes or yes/no responses to indicate that the patient has read and confirmed each acknowledgment and agreement | Possible new transaction for confirmation/certification and notifications. |
| Confirmation | 4.2.2Complete Patient Acknowledgments and Agreements for Initiation of Treatment | Confirmation (e.g., a digital signature) that the patient has read and understood all of the acknowledgments and agreements | Possible new transaction for confirmation/certification and notifications.<br>Review current digital signature requirement in the REMS transaction and make modifications if necessary. |
| Confirmation | 4.2.3 Screen Patient | Confirmation of receipt of information | Possible new transaction for confirmation/certification and notifications. |
| Confirmation | 4.2.3 Screen Patient | Confirmation of whether laboratory test result or other health information is acceptable | Possible new transaction for confirmation/certification and notifications. |
| Confirmation | 4.1.2 Participate in REMS Training/Certification | Confirmation that the training has been completed (if training was provided by a party other than the REMS administrator) | Possible new transaction for confirmation/certification and notifications. |
| Confirmation | 4.1.2 Participate in REMS Training/Certification | Confirmation that completion of the training was adequately documented (if training was provided by a party other than the REMS administrator) | Possible new transaction for confirmation/certification and notifications. |
| Confirmation | 4.1.1 Complete REMS Acknowledgments and Agreements for Certification | Confirmation (e.g., a digital signature) that the health care provider has read and understood all of the REMS acknowledgments and agreements | Possible new transaction for confirmation/certification and notifications.<br>Review current digital signature requirement in the REMS transaction and make modifications if necessary. |
| Confirmation | 4.3.1 Monitor Patient's Condition and Status | Confirmation of whether the result of laboratory test result or other clinical assessment is acceptable | Possible new transaction for confirmation/certification and notifications. |
| Conformation | 4.1.3 Complete REMS Training Questions | Confirmation of whether or not the health care provider successfully answered the training questions | Possible new transaction for confirmation/certification and notifications. |
| Conformation | 4.1.4 Enroll In the REMS | Confirmation of receipt of enrollment information | Possible new transaction for confirmation/certification and notifications. |
| Lab Test or Screening | 4.2.1Complete Prescriber Acknowledgments and Agreements for Initiation of Treatment | The prescriber has conducted necessary laboratory tests or screening | Add the Observation element to the current REMS transactions allowing the prescriber to report the lab values and associated date. |
| Lab Test or Screening | 4.2.3 Screen Patient | Information about the laboratory test, potentially including the date of the test, the time of the test, and the type of test conducted | Add the Observation element to the current REMS transactions allowing the prescriber to report the lab values and associated date. |

| Gap Identified | Section | Text | Solution |
|---|---|---|---|
| Lab Test or Screening | 4.2.3 Screen Patient | Results of the laboratory test | Add the Observation element to the current REMS transactions allowing the prescriber to report the lab values and associated date. |
| Notification | 4.1.2 Participate in REMS Training/Certification | Relevant information needed to obtain continuing education (CE) credit for the training | Possible new transaction for confirmation/certification and notifications. |
| Notification | 4.1.2 Participate in REMS Training/Certification | Information about where to obtain training, including URLs at which health care providers can access web-based training | Possible new transaction for confirmation/certification and notifications. |
| Notification | 4.2.3 Screen Patient | If deemed necessary, alerts to authorize, order and/or change the monitoring frequency/dosing, or to discontinue treatment | Possible new transaction for confirmation/certification and notifications. |
| Notification | 4.2.3 Screen Patient | If deemed necessary, alerts about pending expiration of laboratory tests | Possible new transaction for confirmation/certification and notifications. |
| Notification | 4.3.1 Monitor Patient's Condition and Status | If deemed necessary, alerts to authorize, change the monitoring frequency/dosing, or discontinue treatment | Possible new transaction for confirmation/certification and notifications. |
| Notification | 4.3.2 Verify Safe Use Conditions When Prescribing | Alert if the certain safe use conditions have not been met, including REMS refill restrictions and days' supply restrictions. The alert may be for informational purposes or may serve as a hard stop, preventing prescribing | Possible new transaction for confirmation/certification and notifications. |
| Notification | 4.3.2 Verify Safe Use Conditions When Prescribing | Alert if there are any pending REMS-related deadlines, such as the need to recertify the prescriber or patient or conduct additional monitoring | Possible new transaction for confirmation/certification and notifications. |
| Notification | 4.3.2 Obtain REMS Dispensing Authorization | Reminders to carry out certain actions, such as counseling the patient or dispensing a Medication Guide. | Possible new transaction for confirmation/certification and notifications. |
| Notification | 4.3.2 Obtain REMS Dispensing Authorization | Notification that safe use conditions were not met (i.e., not authorized to dispense) and corrections are necessary for authorization | Possible new transaction for confirmation/certification and notifications. |
| Notification | 4.2.1Complete Prescriber Acknowledgments and Agreements for Initiation of Treatment | Reminder to perform the necessary REMS activities | Possible new transaction for confirmation/certification and notifications. |

Additionally, NCPDP recommends the use of the Structured Product Label (SPL) to communicate REMS requirements to prescribers and dispensers. The SPL should contain links to the educational and/or training materials.

*(4) Where (if at all) do new standards need to be developed?*

**NCPDP Comment:** Each SDO, such as NCPDP, X12 and HL7, should review their current transactions to determine if there is a need to develop enrollment or other transactions for prescribers, patients, pharmacies and pharmacists.

*(5) What other opportunities exist to leverage health IT to facilitate the completion of REMS activities?*

**NCPDP Comment:** NCPDP has identified the following opportunities:

- Ensure the information provided in the transaction will interact with the EHR to minimize manual entry.
- Incorporate lab values into systems as discrete data elements and allow the values to be communicated electronically between the healthcare provider and the REMS administrator. This could be accomplished through the observation elements in the SCRIPT transactions.
- New electronic transactions as referenced in question 3.

**General Comments from the REMS Platform Standards Initiative document:**

**Page 4, Section 3.1 REMs Stakeholders**

**NCPDP Comment:** NCPDP requests that throughout the document 'health care providers' be referred to as 'HCPs.'

**NCPDP Comment:** NCPDP recommends additional guidance be included within the final rule to further explain the exclusion of wholesalers.

**Page 4-5, Section 3.2 REMS Activities**

**NCPDP Comment:** In the paragraph below, please clarify what is meant by "identifying, descriptive, and contact information".

"First, there are activities prescribers, health care settings, or pharmacies may be required to complete in order to prescribe, dispense, administer, or order a drug. Collectively, these activities form a process known as **Certification**. For example, a practitioner wishing to prescribe a drug may be required to provide identifying, descriptive, and contact information to a REMS administrator; complete certain training questions; and agree to carry out certain activities to ensure the safe use of the drug. For health care settings or pharmacies, some of these activities may be carried out by an authorized representative on behalf of the setting rather than by individual health care providers."

**Page 9-10, Section 4.1.3 Complete REMS Training Questions**

**NCPDP Comment:** Many REMS programs refer to training questions as Knowledge Assessment (KA). It may be helpful to include this term in addition to Training Questions in the document.

**Pages 13-14, Section 4.3.1 Monitor Patient Condition or Health Status**

**NCPDP Comment:** NCPDP questions the appropriateness for a REMS administrator to make specific suggestions on next steps with the patient, such as, "changing monitoring frequency/dosing, or discontinuation of treatment". If using the NCPDP REMS transactions, the REMS administrator should reject the REMS request based on criteria, such as high lab values. The response could provide general guidance to the prescriber, such as re-evaluating the patient for appropriateness of drug therapy.

**Page 14, Section 4.3.2 Verifying Safe Use Conditions When Prescribing**

**NCPDP Comment:** Please verify the reference that the dispenser is the dispensing facility.

Additionally, in the statement below, consider changing refills are permitted to refill limitations exist.

- Additional information about the prescription, including the drug, days' supply, quantity prescribed, and whether refills are permitted

NCPDP looks forward to working with the FDA to enhance and improve efficiency of the electronic exchange of information to comply with REMS requirements between healthcare providers and REMS administrators.

Thank you for your consideration of our input.

For direct inquiries or questions related to this letter, please contact:

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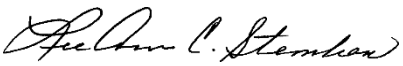
Sincerely,



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