July 20, 2023

Department of Health and Human Services
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2023-N-0573 for Proposed Changes to Third-Party Vendors Establishment of a Public Docket; Request for Comments.

To Whom It May Concern:

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit American National Standards Institute (ANSI) Accredited Standards Developer (ASD) consisting of more than 1,500 members representing entities including, but not limited to, claims processors, data management and analysis vendors, federal and state government agencies, insurers, intermediaries, pharmaceutical manufacturers, pharmacies, pharmacy benefit managers, professional services organizations, software and system vendors 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 business solutions, including ANSI-accredited standards and guidance for promoting information exchanges related to medications, supplies and services within the healthcare system.

NCPDP appreciates the opportunity to review and submit comments to the Food and Drug Administration (FDA) highlighting key factors the FDA should consider when reviewing a proposed Risk Evaluation Mitigation Strategies (REMS) modification prompted by or related to a change in a REMS administrator for a REMS with Elements To Assure Safe Use (ETASU). NCPDP is engaged with REMS stakeholders, working collaboratively with the HL7® CodeX [1]community to mitigate disruptions in patient care by using message standards to reduce undue burden and ensure patients receive their medication in a timely manner.

NCPDP recommends REMS applicants and/or administrators seek input from the following stakeholders prior to developing new or modifying existing REMS systems, processes and data exchanges:

- Prescribers
- Pharmacies
- Patients
- REMS administrators
- Manufacturers
- Wholesalers
- Intermediaries (EHRs/switch vendors)
- Hub processors
- Other REMS vendors

The extent and timing of the input will vary depending on the stakeholder. Any stakeholder needing to complete technical system changes will need time to complete and implement those changes. A minimum

[1] https://confluence.hl7.org/display/COD/Risk+Evaluation+and+Mitigation+Strategies+%28REMS%29+Integration

of six months is needed for implementation, but a twelve month window is preferred. Some of the other changes that will require time to complete include, but are not limited to, account creation, data transfers, call center setup, patient education and training of various stakeholders, data integration, assessment reports and changes to workflow including hub environments. The conversion time estimate considers the design and development, testing, implementation and post-implementation phases of the REMS workflow.

Project Phases with Example Activities

Design and Development	Testing	Implementation	Post-Implementation
• Scope and requirements of both existing and new REMS administrators • Build new platform or create data mapping to the new REMS administrator with FDA review • Connections to all involved stakeholders	• Update to REMS documentation and submission to FDA as needed by the manufacturer • Testing phase to be completed by the REMS administrator and integrated stakeholders • FDA approval of the new REMS administrator's process at least 60 days prior to implementation/go-live date	• Connections to all involved stakeholders • Data migration from existing REMS administrator to the new REMS administrator • Implementation of new process with all stakeholders	• Monitoring of new process
Manufacturer directed communication to impacted stakeholders in all phases			

NCPDP recommends the sponsor and/or REMS administrator conduct testing of all changes to the REMS system and its operation prior to full implementation ("Go Live"). User acceptance testing with stakeholders, evaluation of any unexpected impact on stakeholder workflow and an assessment of REMS data flows is critical and should include assuring REMS data from the existing REMS administrator system can be timely and successfully transferred to and integrated by a new REMS administrator system.

The amount of time needed to transition stakeholders from one REMS system to another REMS system is typically six to nine months but could be as long as twelve months from project start to finish. Before the new system is fully implemented, a transition period is recommended to allow for testing, transfer of enrollment and certification data and recredentialing. Post launch, there is typically a period of about three months of Hypercare (intensive) support for stakeholders through the transition where minor adjustments are made to the program based on live usage.

NCPDP recommends the sponsor and/or the REMS administrator conduct a Failure Modes and Effects Analysis (FMEA) to identify and plan for system failures as a part of the testing process.

We want to note that CodeX is a member-driven community focused on solving one of the most difficult problems in healthcare. CodeX recently initiated an effort to improve REMS drug safety by creating a data infrastructure using community-developed, real-world tested, open standards to pilot an approach to improve the efficiency and effectiveness of the FDA REMS processes through automation. The collaborative goal for NCPDP and CodeX is to explore how providers, pharmacists, health systems, pharmaceutical manufacturers, REMS administrators and patients can interact in meaningful ways through consistent, trusted data. CodeX seeks to automate REMS processes where possible to support the eventual streamlining of medication access, lessening the burden for all stakeholders involved. These standards-based integrations will reduce the time spent by third party vendors in design, development, testing and implementation of new REMS programs and continue to identify gaps and burdens within the existing REMS workflow.

Advancements are happening with HL7® CodeX REMS Integration Use Case and NCPDP's WG19 REMS Workflow to Transaction Task Group, and our comments are not reflective of this ongoing work. The comments above assume the FDA process for REMS administrators remains essentially the same as it is today. As the standardization of clinical data sharing to meet a REMS program is adopted and evolves, the suggested timelines may be condensed. In addition, other responses provided in this letter could be impacted by the ongoing improvement efforts.

NCPDP and its members appreciate this opportunity to provide comments and feedback to the FDA as they relate to REMS programs and would welcome further involvement.

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

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Respectfully,

Lee Ann C. Stember
President & CEO
National Council for Prescription Drug Programs (NCPDP)