REMS Standardization via Structured Product Labeling (SPL):

Critical Codification & Structure for Downstream Automation

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What is NCPDP?

- An ANSI-accredited standards development organization
- Provides a forum and marketplace for a diverse membership focused on health care and pharmacy business solutions
- A member driven organization that has been named in various government legislation and rulings, such as HIPAA and the Medicare Part D Regulation
- One of several Standards Development Organizations (SDOs) involved in Healthcare Information Technology and Standardization
- Focus on pharmacy services, and has the highest member representation from the pharmacy services sector of healthcare
- NCPDP standards are used in pharmacy processes, payer processes, electronic prescribing, rebates, and more
NCPDP REMS Task Groups

• SPL REMS Requirements Task Group
  – Developing template for codified electronic submission of REMS in central repository within FDA’s structured product labeling (SPL) system

• REMS and ePrescribing Task Group
  – Addressing REMS integration into electronic prescribing transactions between prescriber/pharmacy/intermediary/payer/sponsors/REMS Administrators

• Safe Use Processing (FDA REMS) Task Group
  – Defined transaction needs for REMS prescription authorization and processing in claim and reporting standards
The Needs

- No highly structured electronic REMS submission requirement
  - Electronic versions of REMS are PDFs & word-processing documents
- No standardized, granular data structure
- No standardized coding mechanism
- No codified connection with labeling
  - No codified links between DailyMed SPL & REMS info
  - No REMS identifying code within existing SPL (e.g., limitations to use identifier)
- No method to electronically identify and extract REMS requirements for meaningful use
- Downstream automated prescription authorization and processing requires highly structured, codified REMS data
Proposed Solution

• Use SPL as highly structured, granular mechanism for REMS submission, maintenance, ready access, & meaningful use

• Apply data format, content, & coding standards

• Use SPL accessed via DailyMed to allow meaningful data extraction

• Develop standards focused on REMS requirements verification for transactions (e.g., ETASU compliance) for seamless
  – prescription processing
  – claims processing
  – reporting

Property of NCPDP
Why Use SPL for REMS?

- Need for incorporation into workflow & to minimize burden for prescribers, pharmacies, sponsors, and others
- Need for a reliable, standardized source (SPL document) with required elements to safely and effectively use a medication
- REMS information can be extracted easily, automatically, and electronically from an SPL document
- Patients and their safety are the most important reason to standardize REMS information via SPL
Why Use SPL for REMS?

- SPL is an existing, adaptable standard already in use for exchanging meaningful medication information electronically
  - It is well suited for highly granular data like REMS
  - SPL formatting allows a mix of coding & text
  - Highly adaptable substructure

- Existing mechanisms for addressing issues, best practices, standards, & future development

- Effective publically accessible data repository already exists via DailyMed

- Existing expertise & infrastructure to support

- Sponsors have extensive experience in submitting SPL data electronically to central repository
Where Can a Standard for REMS be Derived?

• Initial structure for codifying REMS via SPL was drawn by NCPDP from the Draft FDA Guidance:


• FDA subsequently identified data requirement gaps relative to draft guidance & created internal database that can be used as a foundation for structuring an SPL REMS data standard

• SPL is an existing, adaptable HL7 standard
Why Standardize REMS via SPL?

- Codification of unique components with SPL is a way to organize, standardize, and centralize the content associated with a packaged product (NDC level)
- Would standardize REMS format & content for electronic submission to FDA
- Standardized, granular REMS requirements simplify integration into e-prescribing and prescription processing systems
- Standardized REMS format allows easy inclusion within existing standards such as the NCPDP e-prescribing (SCRIPT) and prescription adjudication and reporting (Telecommunication) standards
- Allows automatic population of public information sites
- Improves FDA and sponsor tracking
- Meets the goals of PDUFA V for standardization that:
  - foster integration into existing & evolving health systems
  - reduce the burden to existing & evolving health systems
Composite REMS SPL

Source Content:
- Labeling
- Pkg Samples
- Med Guide
- PPI
- Drug Listing
- REMS

SPL-LL Document:
- Title
- Highlights (PLR)
- Content of Labeling
- Pkg Label, PDP
- Patient Counseling, Med Guide, PPI
- REMS Content
- Product Listing Table
- REMS Data

Adapted from Gary Saner, Reed Technology
Composite REMS SPL Process

Adapted from Gary Saner, Reed Technology
REMS Exchanges

Property of NCPDP
Benefits of SPL Standardization for REMS

• Standardized & more efficient submission of REMS by sponsors
• More efficient & simplified REMS review by FDA
• More efficient & standardized REMS prescription processing
  – Documenting certification of prescribers, dispensers, health-care settings, etc
  – Qualifying patients
  – Prescribing
  – Dispensing
  – Documenting other elements to ensure safe use (ETASU)
• More efficient & simplified REMS tracking at all levels
• Standardized & optimized REMS reporting and analysis
• Leveraging existing SPL expertise, standards, infrastructure, & publically accessible central repository
NCPDP as a Collaborator

• ANSI-accredited standards development organization involved in electronic prescription workflow

• Widely adopted standards for electronic prescribing and prescription authorization processing and reporting

• Membership by key stakeholders affected by REMS

• Existing Task Groups have been working with FDA and other stakeholders on REMS requirements for > 2 years

• Originally proposed and investigated SPL standardization solution for REMS in collaboration with FDA and other stakeholders

• Already engaged broad-based expert & stakeholder feedback

• Already begun modeling & enhancing REMS integration into affected e-prescribing & telecommunication standards
Recommendations

• Adopt SPL as the means for standardizing and providing central access to REMS data

• Designate development and implementation of SPL standardization of REMS as one of the 4 PDUFA V priority projects
  – All downstream REMS prescription transactions critically depend on timely achievement to greatly reduce health-system burden

• Designate NCPDP & NLM as collaborators
  – Integration into existing e-prescribing & prescription processing standards
  – Leverage existing drug information data repository