REMS Standardization via Structured Product Labeling (SPL):

Critical Codification & Structure for Downstream Automation

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NCPDP

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

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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

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:

  "Guidance for Industry: Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments, and Proposed REMS Modifications – Draft Guidance September 2009"

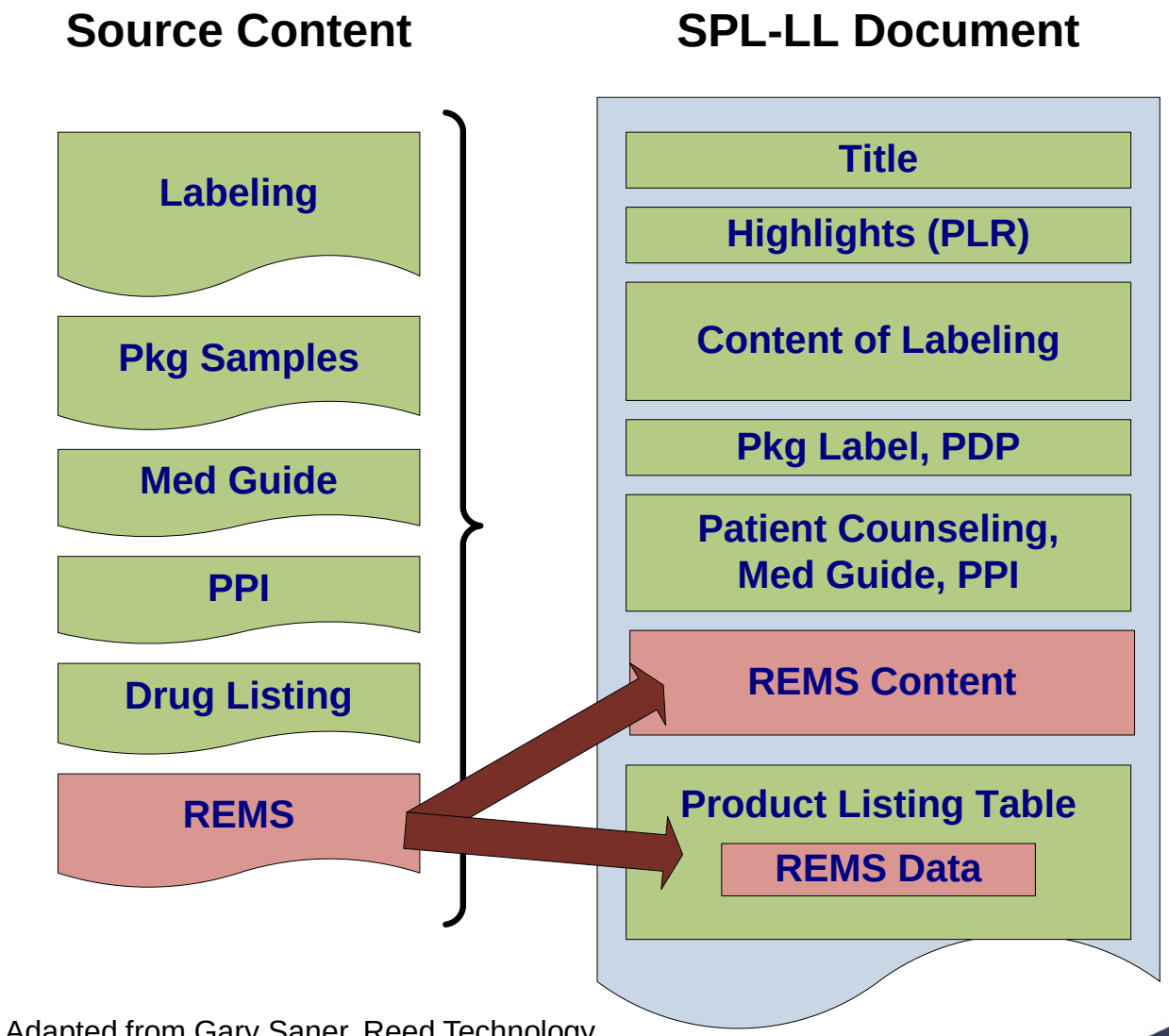
- FDA subsequently identified data requirement gaps relative to draft guidance & created internal database that can be used as a foundation for structuring an SPL REMS data standard

- 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



Adapted from Gary Saner, Reed Technology

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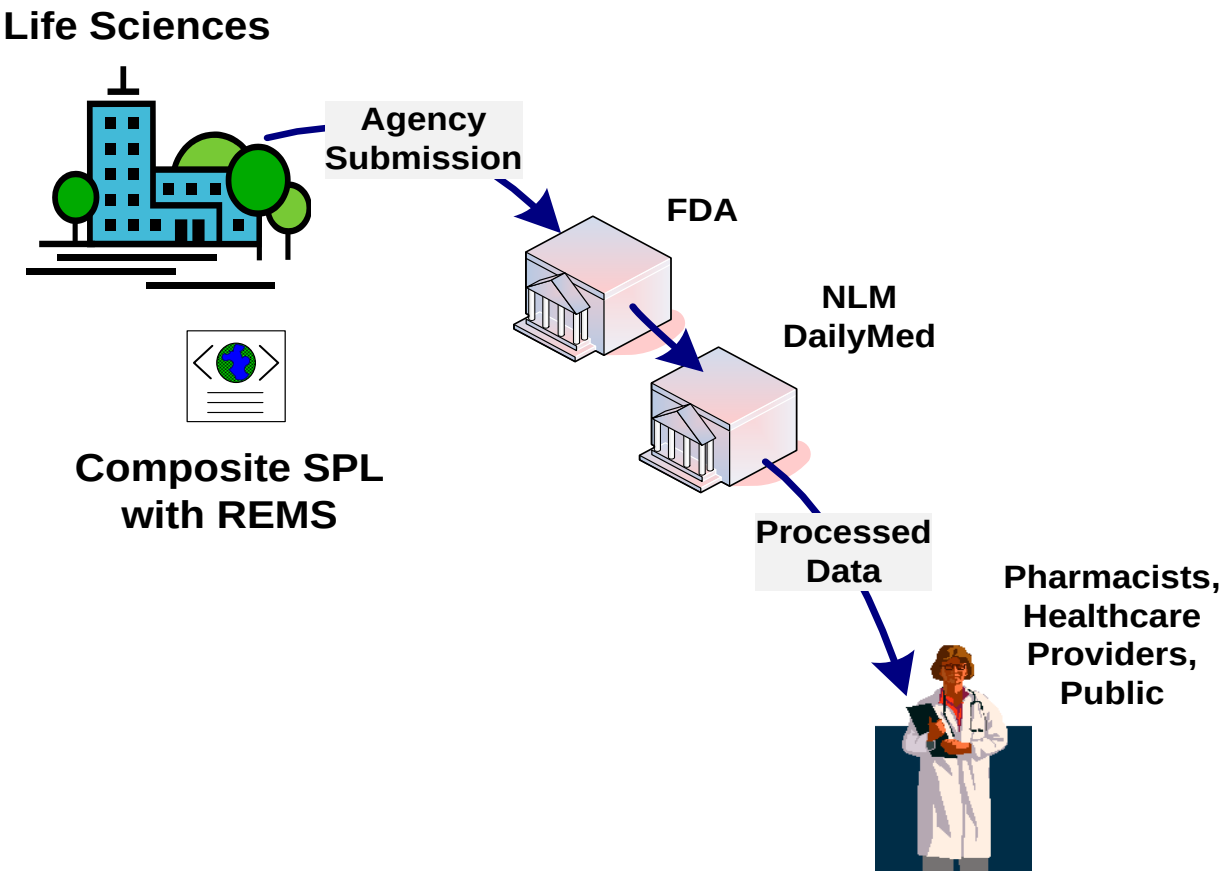
Composite REMS SPL Process



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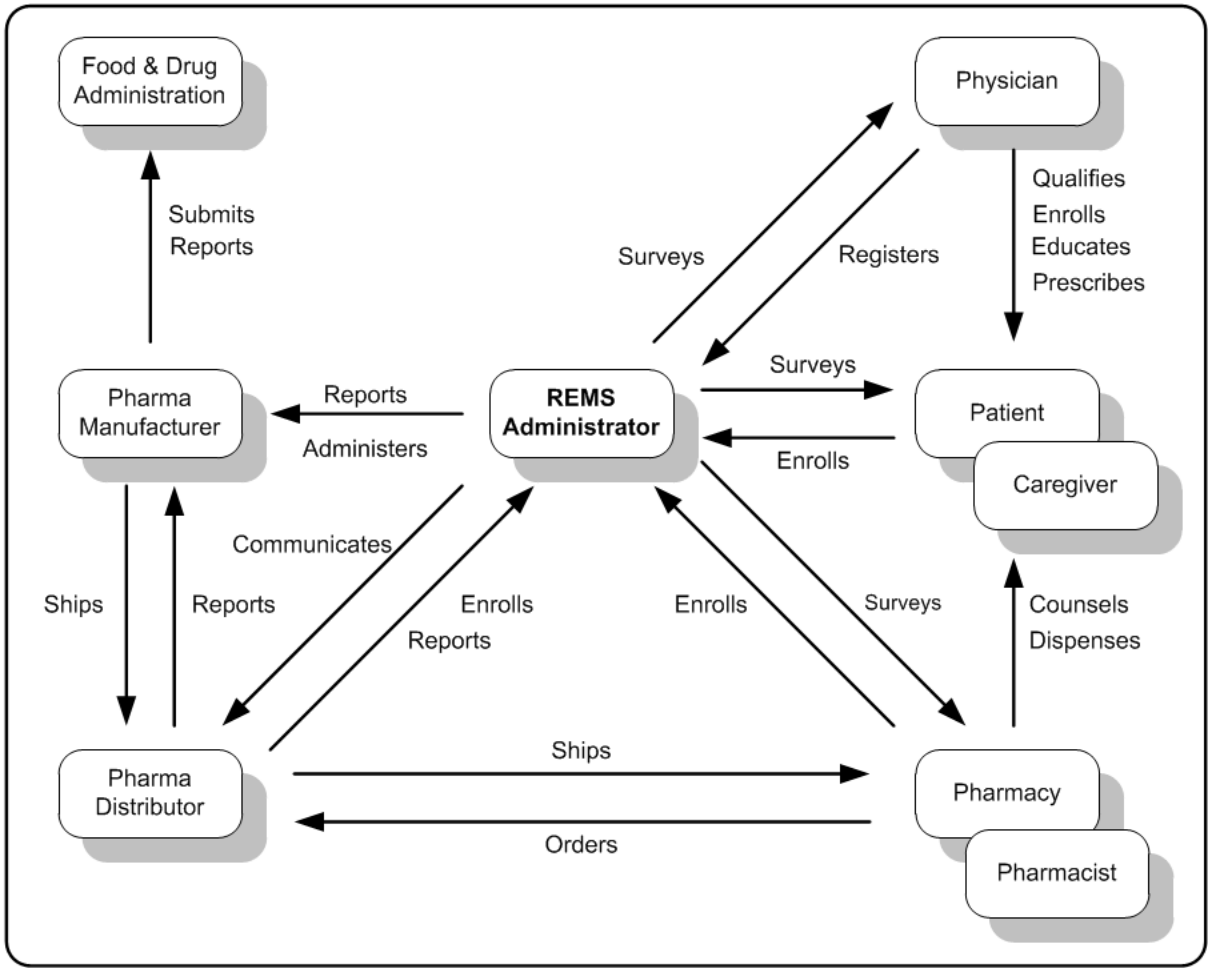
REMS Exchanges



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