FDA REMS Standardization and Evaluation Public Meeting July 25 & 26, 2013

National Council for Prescription Drug Programs (NCPDP) Summary of Oral Comments

Gerald McEvoy, Pharm. D. 5724682680-176327119

The National Council for Prescription Drug Programs (NCPDP) is a not-for-profit ANSI-accredited standards development organization (SDO) consisting of around 1600 members who represent drug manufacturers, pharmacies, drug wholesalers, insurers, mail order prescription drug companies, claims processors, pharmacy benefit managers, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies, and other parties interested in electronic standardization within the pharmacy services sector of the health care industry.

NCPDP will provide oral comments to FDA at its upcoming public meeting on Risk Evaluation and Mitigation Strategy (REMS) standardization and evaluation about the critical importance of establishing as one of the 4 priority projects outlined by PDUFA V the implementation of a standardized, highly structured and codified electronic submission requirement for REMS using the structured product labeling (SPL) model and public access via DailyMed.

Included in NCPDP's comments will be a description of why SPL should be the preferred path to achieving the goal of REMS standardization aimed at better integration with, and a resultant reduction in burden to, the existing and evolving health care system. In addition, NCPDP will comment on the critical role that access to, and repurposing of, such highly structured and codified REMS data has on the downstream achievement of more efficient, highly integrated prescription processing and patient monitoring for affected drug products. Workflow involving the prescriber, dispenser, drug manufacturer and distributor, REMS administrator, registries, processors, and adjudicators all will benefit from NCPDP's SPL strategy for REMS. Implementation of various NCPDP standards on electronic prescribing and other drug product transactions involving REMS depend on timely implementation of an SPL solution.

NCPDP has a long record of supporting the meaningful, highly granular tagging of content of drug labeling and other product data within SPL as a means to enhance the downstream users' ability to automatically search and sort specific, meaningfully tagged information and data. SPL and its associated indexes have proven useful in data mining and population of various drug databases used to drive prescription transactions and other health-system activities involving drug products. NCPDP has collaborated with FDA for several years now in providing valuable feedback on how the agency can

ensure broad-based meaningful electronic use of drug information and data included in and indexed to SPL by a wide variety of stakeholders in a broad range of health-care systems, settings, and applications.

As part of that collaboration, NCPDP first proposed to FDA over 2 years ago through its standards-development Work Groups and Task Groups that the agency explore the merits of using SPL as a means to electronically standardize, codify, and provide ready public access to REMS data. Developing such a strategy is a critical element to ensuring that REMS requirements become incorporated seamlessly into workflow along the continuum from prescribing, authorization, dispensing, and patient monitoring. NCPDP currently has 3 Task Groups charged with implementation of various aspects of REMS standardization, prescribing, and prescription processing.

Over that time, a growing consensus has developed among NCPDP members, FDA staff, the pharmaceutical industry's SPL experts, other SPL experts, and downstream users of SPL that the existing standard for electronically transmitting drug information and data represented in SPL would be the logical implementation strategy for standardizing and codifying REMS information and that the National Library of Medicine's (NLM's) DailyMed website would be the logical publicly accessible repository for the electronic files.

SPL is an existing, adaptable HL7 standard already in wide use for exchanging meaningful drug product information and data electronically. SPL has a highly adaptable structure that is well suited for granular data like REMS and its formatting allows for a mix of coding and text. There currently are existing mechanisms for addressing issues, best practices, standards, and future development of SPL structuring and application as well as an extensive existing level of expertise and infrastructure to support it. In addition, pharmaceutical manufacturers already have a well-established capability for timely electronic submission of other highly structured drug product information and data via SPL.

It is for these and other reasons that NCPDP will advocate strongly in its oral comments for the establishment as one of FDA's 4 priority projects the timely development and implementation of an electronic strategy for submission and maintenance of REMS data via SPL. NCPDP and its members agree that SPL should be the preferred path for electronic standardization and that such data be publicly accessible via DailyMed for meaningful downstream use in support of more efficient and highly integrated processing of REMS requirements.