



December 15, 2006

Food and Drug Administration
Department of Health and Human Services
Docket No. 2005N-0403, **RIN Number 0910-AA49**

The National Committee on Vital and Health Statistics (NCVHS) is pleased to offer its support of the Food and Drug Administration's (FDA) Notice of Proposed Rule Making (NPRM) recommending changes to give the FDA control over the National Drug Code (NDC).

The NCVHS is charged by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) to develop recommendations for uniform standards to enable electronic prescribing (e-prescribing) in ambulatory care. During the past several years, the NCVHS has focused considerable attention on the feasibility and desirability of standards that are necessary to support e-prescribing, and the need for standard terminology for clinical drugs to facilitate automated drug utilization review and decision support for patient safety.

The FDA developed and maintains the National Drug Code (NDC), a 10-digit code that identifies drug products marketed in the United States. The NDC relies primarily on paper-based reports on ingredients, dosage forms, strengths, labeling and other information from manufacturers, relabelers, repackers and distributors to provide details on marketed drug products. FDA uses this information for drug safety and other regulatory purposes. The NDC is used by dispensers to identify a marketed drug product specific to the drug's manufacturer/distributor, dosage, form, and packaging.

In previous reports, the Committee documented NDC shortcomings, most notably the concern about perceived weaknesses of the current NDC database and linkage of the NDC to RxNorm concepts. The Committee expressed the acute need for harmonization of terminologies in the drug area to eliminate incompatibilities that impair drug utilization studies and may negatively affect patient safety.

The Committee advised that HHS include the National Library of Medicine's (NLM) clinical drug terminology, RxNorm, in the 2006 e-prescribing pilot tests to determine how well the prescriber's intent is represented (or preserved) when the RxNorm information is translated from the prescriber's system into the NDC at the dispenser's system. The FDA responded by providing the NLM with Structured Product Labeling (SPL) information, which includes the content of labeling and drug listing data elements, including elements for mapping the NDC to RxNorm.



The FDA also established collaborations with, among others, the Veterans Health Administration, National Library of Medicine, Office of the Assistant Secretary for Planning and Evaluation (ASPE), Agency for Healthcare Research and Quality (AHRQ) and the National Cancer Institute (NCI) for purposes of clarifying federal medication terminology. This included working with NLM to link clinical drug to NDC and distribution of Structured Product Labeling through DailyMed; and working with NCI Enterprise Vocabulary Services to establish the NCI Thesaurus as a source for FDA terminology. FDA and NLM were provided with substantial funding by AHRQ and ASPE for this work, which will improve patient safety.

The Committee also encouraged the promulgation of FDA's drug listing rule to improve the integrity of the NDC and support the correlation of NDC with RxNorm. In recent testimony before the NCVHS Subcommittee on Standards and Security, the FDA confirmed that the current NDC database is not adequate to be an authoritative source, and additional testimony from NLM confirmed that RxNorm linkage to NDC is currently complicated by this lack of an authoritative source. On August 20, 2006, the FDA published a Notice of Proposed Rule Making (NPRM) in the Federal Register (Vol. 71, No. 167, Docket 2005N-0403) recommending changes that would allow FDA control over the NDC and would result in a complete and authoritative source of NDC numbers. The NPRM would make the complete list of drug products marketed in the United States readily accessible electronically, providing for accurate, unique, and unambiguous NDC numbers for each drug. This would allow electronic systems to reliably and consistently link the NDC number to the appropriate drug labeling through Structured Product Labeling (SPL). The drug labeling would supply the drug ingredient and other information necessary to support the development of the standards for medication terminology necessary for electronic prescribing. As such, the proposal would provide important support for the full implementation of the electronic prescription provisions of the Medicare Modernization Act.

The NCVHS commends the cooperation of the FDA and NLM as they address these issues and the support of AHRQ and ASPE. The NCVHS agrees with the provisions of the NPRM and recommends that the final rule contain these provisions and be published as soon as possible, so that it can foster the resolution of those NDC issues previously identified as problematic.

Sincerely,

/s/

Simon Cohn, M.D., M.P.H.
Chairman, National Committee on Vital
and Health Statistics