January 14, 2011

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Comments should be sent to *SOS_RFI@nist.gov* with the subject line ‘‘Standardization feedback for Sub-Committee on Standards.’’

Re: Standardization feedback for Sub-Committee on Standards

Dear NIST;

The National Council for Prescription Drug Programs (NCPDP) submits the following comments regarding the Department of Commerce, National Institute of Standards and Technology [Docket No. 0909100442–0563–02] Effectiveness of Federal Agency Participation in Standardization in Select Technology Sectors for National Science and Technology Council's Sub-Committee on Standardization Request for Information.

NCPDP is a not-for-profit ANSI-accredited Standards Development Organization consisting of more than 1,550 members who represent drug manufacturers, chain and independent 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.

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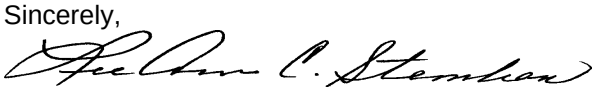
Sincerely,



Lee Ann C. Stember
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cc: NCPDP Board of Trustees

The Sub-Committee on Standards is specifically interested in comments that address the questions below as they relate to the following technologies:

1. Smart Grid.
2. Health Information Technology.
3. Cyber Security.
4. Emergency Communications Interoperability.
5. Radioactivity Detectors and Radiation Monitors (ANSI N42.3x and N42.4x).
6. Other technologies involving significant Federal agency participation in standards setting.

**NCPDP Response:**

NCPDP's comments will be focused on 2. Health Information Technology and 4. Emergency Communications Interoperability.

4. Emergency Communications Interoperability

NCPDP would like to make you aware of the significant industry collaborations of RxResponse (www.rxresponse.org) and ICERx (www.icerx.org) for emergency situations.

Rx Response partners work with local, state and federal officials as well as volunteer organizations to help support the continued delivery of medicines to people who need them in the event of such an emergency – whether it is caused by a natural disaster, terrorist incident or health emergency such as a pandemic. Rx Response provides an information-sharing and problem-solving forum for the private pharmaceutical supply system, disaster relief agencies and government to help ensure the continued delivery of critical medicines to patients whose health is threatened by a severe public health emergency. Rx Response relies on the existing pharmaceutical supply system to provide for the continued flow of medicine in a major public health emergency. This collaboration consists of private and public organizations, federal agencies, and NCPDP is proud to be a contributor.

ICERx.org (In Case of Emergency Prescription Database) is a public-service online resource developed by the healthcare industry to help ensure continuity of quality care for the victims of future disasters. Once authenticated, licensed prescribers and pharmacists caring for patients in an emergency situation will be able to securely access a patient's medication history.

Recognizing that stakeholders participate in standards-setting activities for varying reasons, and in order to evaluate the effectiveness of Federal agencies' participation in standards-setting efforts led by the private sector, the Sub-Committee invites organizations to provide information on their participation, and their perceptions of Federal participation in standards-setting activities related to the case-study technologies listed above, as well as the current status of the standardization process for these technologies. The Sub-Committee is interested in better understanding: Who participates in standards-setting activities? What are the most important reasons for participation? What are the benefits of developing standards for this sector? How do the standards impact organizations and their competitiveness? How has standardization spurred innovation in the technology sector(s) that is the subject of your comment? What is the current phase of the standards development process for this technology? How has the process worked so far? When developing standards, how are the standards-setting processes managed and coordinated? Is there a strategic plan that identifies the standards needs and defines the standards development life cycle? Are there barriers to developing high level strategies for standard-setting activities?

**NCPDP Response:**

NCPDP takes its mission very seriously to bring together the different stakeholders in health care, specifically pharmacy and the electronic prescribing industry sectors to solve industry business requirements. It cannot be stressed enough that federal and state agencies need to be actively involved in the standards development process.

Specific collaborations include working with the FDA representative on the National Drug Code (NDC), the Structured Product Label (SPL), the Medication Guides (MedGuides), and an Overfill issue.

The Medicare Part D program has been successful in part due to the overwhelming collaboration of the industry with the CMS staff to address questions and problems, and to discuss upcoming and future considerations before implementation. This has led to questions being addressed pre-implementation versus post-implementation, clearer guidance being published, and successful collaboration amongst organizations and with CMS – all leading to better processes in patient care. NCPDP has also witnessed an increase in participation from state agencies as they are directly impacted by Medicare Part D processes.

The electronic prescribing industry has always collaborated to bring united recommendations forward to NCVHS, HHS and the DEA. NCPDP worked with NIST representatives to provide timely, concise, meaningful use test criteria for electronic prescribing and NCPDP continues to assist with questions for timely support. The VA has been an active participant and collaborator on modeling foundations for standards in NCPDP. Representation from the NLM on RxNorm has been extremely valuable for building collaboration with drug database companies and assisting the industry in answering questions regarding the use of RxNorm vocabulary in electronic prescribing functions. This collaboration resulted in consistent recommendations for NCPDP standards being brought forward and approved by the industry. Participants from NCI has been invaluable in creating subsets of medication terminology for use in electronic prescribing, in providing educational information on the use of the terminology, and answering questions.

NCPDP sincerely values the representatives from the agencies who are able to participate as members. These members value the privileges of membership – access to all the documents NCPDP produces, free attendance at NCPDP work group meetings, member rates at educational and conference events, networking opportunities, and other member benefits. Much of NCPDP work is done via task groups under the auspices of the work groups. Task groups meet via conference calls and webinars. NCPDP task groups are open to *any materially interested party*, whether member or not, so that subject matter experts may participate in work underway. We value their expertise in contributing to work products that reflect industry input. These collaborations bring forward different perspectives and have provided further networking opportunities for entities with similar interests.

NCPDP cannot stress the importance of these entities participating as members, and bringing subject matter expertise to the task group calls. When NCPDP receives questions from the industry, a relationship is established to start the dialogue and find a solution. Documentation can then be updated to assist implementers with similar questions.

Intellectual Property

**NCPDP Response:**

NCPDP standards documents are copyrighted. They represent the work of the membership body. NCPDP receives some of its funding from membership, which allows us to offer other benefits to the members at no cost or a reasonable cost. Members may copy and use the work or any part thereof in connection with the business purposes of the Council members. The work may not be changed or altered and may not be sold, used or exploited for commercial purposes.

The success and limitations of standards-setting activities and the associated outcomes may be studied, understood and implemented for continuous process improvement. Such improvements can help ensure that Federal agencies participation in standards activities is cost-effective and will lead to optimal results.

**NCPDP Response:**

NCPDP recognizes the importance of representation from the agencies participating as members, and bringing subject matter expertise to the task group calls. The unique needs of the agencies are part of the discussion when standards are being developed or

problems are being resolved. When NCPDP receives questions from the industry, a relationship is established to start the dialogue and to find a solution. The networking opportunities participation in NCPDP provides are extremely important to all entities. Our collaborative goals are to use standards and vocabularies in a consistent manner to provide patient care.