April 18, 2012

Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities
Office of Management and Budget
Jasmeet Seehra
Office of Information and Regulatory Affairs
jseehra@omb.eop.gov

Re: Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities

Dear Office of Management and Budget,

The National Council for Prescription Drug Programs is providing the following comments to Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities. NCPDP is responding to certain topics.

NCPDP is a not-for-profit ANSI-accredited Standards Development Organization consisting of more than 1,600 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.

NCPDP, as an ANSI-accredited Standards Development Organization follows a development process of standards and other documents that allow for review and approval at multiple points. Most of the standards and other documents are developed via task groups, which are open to any materially interested party, whether member of NCPDP or not, via conference call. As a task group brings forward a standard or modification, it is discussed during quarterly work group meetings which are free or at a reasonable cost to attend. When a standard moves to ballot, again any materially interested party, whether member of NCPDP or not is able to obtain the ballot information either free or at a reasonable cost. If a standard is to move through the federal regulatory process (such as a HIPAA-named standard), the request is brought to the Designated Standards Maintenance Organizations (DSMO www.hipaa-dsmo.org). DSMO requests are reviewed by organizations which includes any materially interested party. Recommendations from the DSMO are taken to the National Committee on Vital and Health Statistics (NCVHS) who hold public hearings on the requests, and make recommendations to the Secretary of Health and Human Services. With publication in the Federal Register, another opportunity for public comment is available.

It is important to note that NCPDP, like other SDOs, is a not for profit organization that puts revenue from the sale of standard publications and products back into the standard development organization services and products. The funds are utilized in the ongoing development and maintenance of standards for infrastructure costs such as staff, meeting administration, and publishing.

How often do standards-developing bodies review and subsequently update standards?

NCPDP Comment: Requests for standards enhancements are accepted, reviewed, balloted, and if approved, published up to four times per year. Therefore any individual

standard may be updated up to four times a year. This quarterly cycle is to meet the needs of industry to react to new business requirements. Upon publication of a standard, the industry has recommended a 180-day period to prepare for implementation. For standards not named in regulation, the implementation period is determined by industry need. The regulatory process does affect this timeframe, such as when the HIPAA process outlined above is invoked (SDO-DSMO-NCVHS-HHS-Industry implementation).

Is there a role for OMB in providing guidance on how Federal agencies can best manage the need for relevant regulations in the face of changing standards?

NCPDP Comment: NCPDP requests that incorporation by reference modify the requirement of having to name a specific version of a standard. The regulation can name the standard for a given purpose, but the industry via other public forums should be allowed to move from one version of a standard to a higher version of a standard without having to go through the lengthy APA process. With the publication of a notice, the government could provide notice of the industry intent to seek input to move to a newer version of a standard. Then the publication of final rule would provide notice of the effective, transition, and implementation dates for the industry.

Should OMB provide guidance to agencies on when it is appropriate to allow the use of more than one standard or more than one conformity assessment procedure to demonstrate conformity with regulatory requirements or solicitation provisions?

NCPDP Comment: It is recommended that OMB let the industry provide input to standards chosen via public comment periods, town halls, NCVHS hearings (healthcare) as appropriate. In addition, it is strongly recommended that, government agency representatives participate in the standards development process and work underway - before standards are regulated. Exposure to the real issues, the challenges of the industry, and the methods by which they work through problems is a valuable asset to the government representative.

Today, certain government agencies mandate which standards and what functionality must be used in electronic health records and for select administrative transactions (HIPAA, MMA, ACA). In addition, government agencies that are involved in healthcare and administrative functions participate as equal members in the standards development process.

Is lack of access to standards incorporated by reference in regulation an issue for commenters responding to a request for public comment in rulemaking or for stakeholders that require access to such standards?

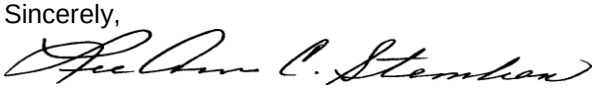
NCPDP Comment: Providing information exclusively on the internet does not create a digital divide, since there are a number of public sites offering internet access today, for example public libraries. It should also be noted that entities can still participate in NCPDP task groups noted above, via conference call. Standards can be obtained via CD. Further, the use of the Internet does not imply products are automatically free. NCPDP also allows the ability to share the published standards within an organization.

NCPDP appreciates the ability to publicly comment.

For direct inquiries or questions related to this letter, please contact
Lynne Gilbertson
VP, Standards Development
NCPDP
Direct:
1803 Longview Drive

Mount Juliet, TN 37122
P: (615) 754-0445
E: lgilbertson@ncpdp.org

Sincerely,



Lee Ann C. Stember
President
National Council for Prescription Drug Programs (NCPDP)
9240 E. Raintree Drive
Scottsdale, AZ 85260
(480) 477-1000 x 108

cc: NCPDP Board of Trustees
cc: NCPDP Standardization Co-Chairs