National Council for Prescription Drug Programs
NCPDP

May 10, 2014

Request for Comments on a Proposed Revision of OMB Circular No. A–119, ‘‘Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities’

NCPDP Response

The National Council for Prescription Drug Programs (NCPDP) is a not for profit American National Standards Institute (ANSI)-accredited Standards Development Organization consisting of more than 1,600 members who represent chain and independent pharmacies, drug wholesalers, insurers, mail order prescription drug companies, pharmaceutical claims processors, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies, drug manufacturers and other parties interested in electronic standardization within the pharmacy services sector of the health care industry. To lean more about NCPDP visit www.ncpdp.org

NCPDP and its members work with government agencies at the federal, state and local levels to achieve optimum compatibility between government laws and regulations and the voluntary consensus standards of industry and commerce, as well as ensuring that voluntary consensus standards provide for government requirements in their procurement of goods and services. The key to a successful partnership is active participation, which requires support and resources from government policy makers at all levels.

NCPDP recommends that public policy should build upon the demonstrated successes in this area and continue to encourage government, consumers, industry, and voluntary standards developers to rely upon the public-private partnership model to explore consensus-based solutions to key national priorities.

NCPDP strongly supports the recommended preference for voluntary consensus standards, especially ANSI-accredited standards. ***NCPDP supports the recommended revisions and clarifications submitted by ANSI in their response letter.***

As named in HIPAA regulation, the Designated Standards Maintenance Organizations (DSMO) was established (www.hipaa-dsmo.org) for modifications in HIPAA named transactions and code sets. NCPDP is a named organization. The HIPAA regulatory process is laborious and does not allow for flexibility of implementation. As part of recommendations to NCVHS and HHS, the three standards development organizations (SDOs) recommended that

> “HHS will publish notice in the Federal Register of SDO work beginning on new versions. This is intended to reach the widest possible audience, as industry’s input is imperative at the development and approval stages of implementation specification development process”
> Reference: http://www.ncpdp.org/Resources/Hipaa-Resources.aspx “Streamlining HIPAA”.

It is important for the industry and SDOs to be involved in government requirements for new or revised regulations at the exploratory time **before** the beginning of the regulatory process and in time to update standards to meet government requirements before final regulations are promulgated. We know this works from an NCPDP perspective and government active involvement in HIPAA and MMA both in the electronic prescribing and Medicare Part D processes. Discussion of industry practices, standards available for usage, and other conversations improved (and continues to improve) the regulations and guidance that are produced. Such an arrangement benefits the government and the private sector with a more precise implementation between standards and regulations. One important success is the Medicare Part D program and its use of standards, industry guidance, and vetting of questions and problems by the industry with the federal partners.

It is unfortunate when some government agency representatives are given permission to attend standards development meetings in some cities, but not other cities. The effective industry collaboration suffers when the government representatives are not allowed to attend ***proven industry meetings***. NCPDP recommends that

the revisions to OMB Circular A-119 include a strong reminder to all federal agencies to give adequate priority to the budget needed for participation in standards work.

NCPDP supports the recommended actions for protection of the voluntary consensus standards' intellectual property and copyright as reasonable. While the possible factors for agencies in determining whether a voluntary standard is "reasonably available", they should only be treated as suggestions, as the agency cannot dictate how a voluntary consensus standards organization operates.

NCPDP operates as a not-for-profit association with funds such as but not limited to membership dues, meeting registration fees, delivery of membership services, provider services, joint ventures, sponsorship opportunities, publication sales fees and standards subscription fees. With NCPDP yearly membership, the member receives all of the documents NCPDP publishes, including updates. NCPDP members attend quarterly face to face work group meetings for no charge, and educational programs and annual conference at a member rate. NCPDP has maintained a reasonable membership fee, while encouraging industry participation to create standards for the pharmacy industry sectors. The NCPDP Work Groups, in order to complete work projects, will create Task Groups with appointed designated Task Group Leaders. Work by the Task Groups are accomplished between Joint Technical Work Group (meetings via conference calls/emails) and reported back to the controlling Work Group at the next meeting. Members and non-members may participate and subject matter experts from companies are most welcome to join in the calls and in the creation of the work product.

NCPDP supports the questions and an answer raised, but offers the following input regarding specific items.

7. **What Is The Policy For Federal Participation In Voluntary Consensus Standards Bodies?**

g. **Are there any limitations on participation by agency representatives?**

In order to maintain the independence of voluntary consensus standards bodies, agency representatives must refrain from involvement in the internal management of such organizations (e.g., selection of salaried officers and employees, establishment of staff salaries, and administrative policies). Agency representatives must not dominate such bodies, and in any case are bound by voluntary consensus standards bodies' rules and procedures, including those regarding domination of proceedings by any individual. Regardless, such agency employees must avoid the practice or the appearance of undue influence relating to their agency representation and activities in voluntary consensus standards bodies.

It is not clear if the above provides guidelines about participation on the **boards** or **ruling bodies** of voluntary consensus standards bodies. There is something stated in

d. **Must agency participants be authorized?**

…While we anticipate that participation in a committee that is developing a standard would generally not raise significant issues, participation as an officer, director, or trustee of an organization would raise more significant issues.

Attributes of a VCS Development Process

It is recommended that the OMB changes still align with the ANSI Essential Requirements as these are very important tenets in long positive industry use.

For questions directly on this topic, please contact:

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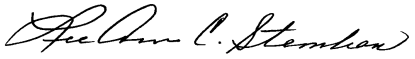
We appreciate the opportunity to submit comments.

Sincerely,



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cc: NCPDP Board of Trustees