March 20, 2012

Incorporation by Reference
Office of the Federal Register (NF)
The National Archives and Records Administration
8601 Adelphi Road
College Park, MD

Re: 1 CFR Part 51 [NARA 12–0002]

Dear Office of the Federal Register,

The National Council for Prescription Drug Programs is providing the following comments to 1 CFR Part 51 [NARA 12–0002].

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 development of standards requires infrastructure - staff, meeting administration, publishing and maintenance to standards - that are costs that facilitate how the work is accomplished. In addition, one class of users should not benefit by another class of users that devoted resources to create the standards.

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. If certain government agencies paid the fair market value for the distribution of developed standards, there is a

possibility that the government would want to have an unfair influence on the standards development process and the standards.

Questions were posed about the entities without internet access. Providing information exclusively on the internet would 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 does request 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.

NCPDP appreciates the ability to publicly comment.

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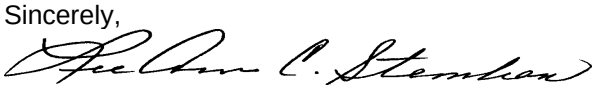
Sincerely,



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cc: NCPDP Board of Trustees
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