



Administrator

Washington, DC 20201

July 13, 2020

William W. Stead, M.D.
Chair, National Committee on Vital and Health Statistics
3311 Toledo Road
Hyattsville, MD 20782-2002

Dear Dr. Stead:

Thank you for your letter to Secretary Azar in which you provided recommendations for the Department of Health and Human Services (HHS) to take actions that could improve the adoption of standards under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Secretary appreciates the work of the National Committee on Vital and Health Statistics (NCVHS) and he has asked me to respond to you on his behalf.

HHS values the role of the NCVHS in bringing together industry experts from all health care segments and facilitating an open dialogue to better understand the important policy, business, and technical issues that need to be addressed to improve the adoption of standards under HIPAA. We agree it is vitally important that HIPAA covered entities are able to meet evolving business needs.

The NCVHS has asked that we provide guidance on the data that is needed to support the adoption of standards. A federal regulation proposed in the Federal Register must include a Regulatory Impact Analysis that identifies the investments necessary to initially implement the rule, the ongoing costs of compliance with the rule, and the savings and benefits of the rule, both initially and over time. For example, HHS finalized a rule “Administrative Simplification: Modification of the Requirements for the Use of Health Insurance Portability and Accountability Act of 1996 (HIPAA) National Council for Prescription Drug Programs (NCPDP) D.0 Standard” that contains a regulatory impact analysis (85 FR 4236, 4240). It may be helpful to review that analysis to understand the kind of information required and how it is presented. Were the NCVHS to submit such data along with its recommendations for adoption of new standards, it likely would help to speed up the adoption process.

The NCVHS asked that HHS secure support for testing and evaluation of standards and operating rules prior to adoption. The NCVHS and Standards Development Organizations (SDOs) play an important role in advising HHS about standards adoption and the more information the NCVHS can provide to support its recommendations, the more helpful it is to HHS. HHS looks to the NCVHS and the SDOs to provide necessary data, support for testing, and evaluation of standards that HHS considers in adopting standards through the rulemaking process.

Your letter recommends that HHS facilitate a more nimble approach to standards development to better support federal policy objectives, industry business requirements, and emerging technologies. HHS recognizes the rapidly changing health care environment, as well as the efforts of the SDOs to

update their processes to be more responsive to those changes. We agree that it is important to make sure that input is received from small entities prior to the NCVHS making recommendations to HHS. We expect that the SDOs and the NCVHS will gather feedback on recommended standards from all applicable segments of the industry, including small entities such as state and local public health agencies and small health plans. Further, the federal rulemaking process allows for full public participation and provides adequate time for HIPAA covered entities to come into compliance with new requirements.

We look forward to continued dialogue on these important matters as we all work to reduce industry burden and promote innovation. Again, thank you for your recommendations.

Sincerely,

A solid black rectangular box used to redact the signature of Seema Verma.

Seema Verma