



William W. Stead, M.D., Chair  
National Committee on Vital and Health Statistics  
Re: NCVHS Recommendations on New Approaches to Improve the Adoption of National Standards for the Health Care Industry

Dear Dr. Stead,

Thank you for your letter including the recommendations from the National Committee on Vital and Health Statistics (NCVHS) to reform the national standards process for the health care industry. I appreciate the expertise and hard work of the NCVHS as it developed these recommendations to support the Department's goals and to improve the efficiency and timeliness of adoption of and updates to standards and operating rules. We have given careful consideration to the Predictability Roadmap and will continue our efforts to keep pace with changing business needs and to take advantage of opportunities for innovation.

In reviewing your recommendations, I would like to raise the following for your consideration:

***Recommendation 1.*** *Remove the regulatory mandate for modifications to adopted standards and move towards industry-driven upgrades.*

The requirement for modification and adoption of standards through regulation is mandated by federal statute, both the Health Insurance Portability and Accountability Act (HIPAA) and the Administrative Procedures Act (APA). While we support activities to encourage development of upgrades by the industry, without statutory changes enacted by Congress we must continue to adopt new standards and modifications through regulatory action. We do have a project underway to expedite the development and promulgation of such regulations.

***Recommendation 2.*** *Promote and facilitate voluntary testing and use of new standards or emerging versions of transactions or operating rules.*

We do support the voluntary testing and use of new standards and versions of transactions and operating rules. Regulation at 45 CFR 162.940 Exceptions from standards to permit testing of proposed modifications, allows for such voluntary testing among willing participants. Testing under this provision can be a valuable source of information as the NCVHS and the Department consider regulations which would adopt such standards.

***Recommendation 3.*** *Improve the visibility and impact of the administrative simplification enforcement program.*

In 2019 we are expanding our enforcement program to include proactive compliance reviews of randomly selected covered entities. These reviews will be based on the entities' compliance with regulatory requirements for HIPAA administrative simplification. Standards and operating rules which are not codified in regulation cannot be subject to enforcement.

**Recommendation 4.** *Provide policy related guidance from HHS regarding administrative standards adoption and enforcement.*

During 2018 HHS developed new communications tools to clearly communicate guidance and information on administrative simplification. These tools were announced to the industry, our stakeholders and the public through an Information Bulletin issued in July 2018, which can be found here: <https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/Subregulatory-Guidance/Downloads/InauguralInformationBulletin.pdf>.

**Recommendation 5.** *Re-evaluate the function and purpose of the Designated Standards Maintenance Organizations (DSMO).*

We agree that it may be beneficial to review how the DSMOs contribute to the adoption and modification of standards, and to determine if there are ways to maximize their impact.

Your recommendations are being further analyzed by the CMS Office of Information Technology, Program Management and National Standards Group, Division of National Standards (DNS). Mr. Madhu Annadata, Director of DNS, in consultation with his leadership and staff, will be working with you to further evaluate each of your recommendations and to explore viable plans for implementing appropriate changes. Mr. Annadata will contact you in the near future to discuss next steps for the Predictability Roadmap.

Again, thank you for your thoughtful recommendations to help HHS achieve our goal of reforming, strengthening, and modernizing the Nation's healthcare system.

Sincerely,



**Cora Tracy**  
Director  
Program Management & National Standards Group  
Office of Information Technology  
Centers for Medicare & Medicaid Services (CMS)

CC: Madhu Annadata