



Statement To
DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS
SUBCOMMITTEE ON STANDARDS

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Members of the Subcommittee, I am Don Bechtel, Health Services Patient Privacy Officer for Siemens Medical Solutions, USA and Chair Elect of the Workgroup for Electronic Data Interchange (WEDI). I would like to thank you for the opportunity to present testimony concerning Operating Rules.

WEDI convened a Subworkgroup to discuss Operating Rules, through which the following initial thoughts have been developed. However, considerable discussion and evaluation still needs to occur within the industry due to the varying needs of the different stakeholders.

WEDI Perspective:

- The concept of operating rules needs to be defined in the context of a broader framework that includes standards, and business operating rules. In addition, the relationship to certification is identified below:
 - Standards --This includes the definition of transaction technical structures, business use case, data elements and business rules associated with the data content within the transaction structure. The responsibility of these activities needs to reside within the existing Standards Development Organizations (SDOs).

- Business operating rules – This includes technical and logistical procedures for any two specific stakeholders to exchange transactions in accordance with the defined standards. The regulations cite “that are not defined by a standard or its implementation specifications”¹. This might include, but is not limited to: communication protocols, service level / performance metrics, security interchange procedures, etc. The specific scope of business operating rules needs to be defined and could be assigned by industry, under the auspices of Health and Human Services (HHS), to specific industry groups for final recommendations. Development of operating rules must be coordinated with the SDOs responsible for the transactions.
 - Certification – If the Secretary chooses to use certification as a method of compliance documentation², entities selected for this role must be stand-alone, i.e. separate entities from those developing the standards or operating rules under these provisions.
- The introduction of any new processes or establishment of new organizations to support the implementation of standards cannot lengthen the implementation process.
 - The goal of these new processes and development entities should be to minimize additional costs in order for industry stakeholders to participate, i.e. participation fees and/or published document purchase fees. Broad industry participation in these entities should be encouraged, by minimizing the costs of participation.
 - Subsequent implementations of operating rules should be aligned such that the standards and operating rules can be accommodated in a single implementation.
 - The industry needs to leverage organizations and capabilities already in place today and avoid additional layers of activities that will further extend or contradict the current consensus building processes.

- The existing SDOs are accountable for the definition and maintenance of technical standards through their existing processes, which serve the purpose of satisfying business use cases between participating health care organizations. Any fragmentation of this process among multiple organizations will result in needless resource / time expenditures, incremental costs and confusion to affected health care organizations.
- Companion Guides establish the foundation for operating rules. Utilizing a companion guide template, such as that currently being developed jointly by WEDI and ASC X12 will insure uniformity industry-wide and reduces stakeholder risk of violating copyrights.

Conclusion

WEDI recommends that HHS take the following actions:

- Reaffirm the advisory role of WEDI to HHS under the Health Insurance Portability and Accountability Act (HIPAA).
- Reaffirm the role of current SDOs in the industry and the oversight role already provided by the Designated Standards Maintenance Organization (DSMO) and NCVHS.
- Develop the process that will define the scope of operating rules.
 - Stakeholders need a clear understanding of the scope in order to address operational implementations between two stakeholders that are exchanging established transaction standards.
 - The work of operating rules cannot address data content or the rules around the content usage.

WEDI seeks to understand what the next steps are for HHS and NCVHS and offers to provide assistance where appropriate. WEDI, in its advisory role, is ready and willing to provide information as warranted to HHS and NCVHS on these matters. WEDI is also ready to collaborate with the entity or entities identified to develop operating rules to provide the education and outreach arm to the industry.

Members of the Subcommittee, thank you for the opportunity to testify.

Citations

1.
Patient Protection and Affordable Care Act., Pub. L. No. 111-148, §1104, 124 Stat. 119, p. 29 (2010).

2.
Patient Protection and Affordable Care Act., Pub. L. No. 111-148, §1104, 124 Stat. 119, p. 31-32 (2010).