University of Chicago
Department of Anesthesia
and Critical Care

Cognitive
technologies
Laboratory

30 April 2009

Harry Reynolds, Jr. Chairman
National Committee on Vital and Health Statistics

Re: Hearing on "Meaningful Use" of Health Information Technology

Dear Mr. Reynolds:

The pursuit of a seamless, comprehensive electronic healthcare record is a worthy goal and the NCVHS assessment of meaningful use is an important contribution to that end. To achieve meaningful use, future systems should be developed, tested, and maintained consistent with good manufacturing process and the operation and performance of these systems should be carefully monitored.

The clinical healthcare information technology proposed by this committee will perform critical medical functions. Yet systems that have been developed and demonstrated to date are riddled with software faults and design deficiencies that reflect the haphazard and uncontrolled fashion in which their components are developed and integrated. Little attention has been given to the human factors of these systems in use and the performance of these critical information technologies is not disclosed or even meaningfully tracked. Although these issues have been raised often over the past decade, there has been no substantive action to address these problems.

To achieve President Obama's goal of putting an effective and robust clinical healthcare information technology system into widespread use in the United States it is critical that the NCVHS provide meaningful oversight and guidance to this process. For that reason, I respectfully recommend that the NCVHS take the lead role in assuring the quality of these future systems by doing the following things:

1) Establish an independent council of advisors with expertise in human factors, computer software and hardware risks, and human clinical performance to address the human factors of clinical healthcare information technology systems in use. The members of this council should be recognized experts without commercial or organizational ties to clinical healthcare information technology entities.

2) Instruct the council to prepare a yearly report to the NCVHS on the state of computerized health information technology and (a) provide assessments of the adequacy of the reliability, broadly construed, of these systems in clinical use; (b) identify emerging vulnerabilities or risks within system-of-systems comprising the national clinical healthcare information technology infrastructure; (c) propose approaches or methods capable of addressing the vulnerabilities or

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risks; (d) recommend to the NCVHS the types of research and inquiry likely to be useful in creating and sustaining robust performance of the infrastructure in the future.

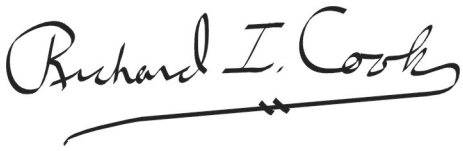
3) Instruct the council to establish and operate an independent, national clinical healthcare information technology patient safety organization (PSO) under 42 CFR Part 3 to accept and analyze reports of problems with clinical healthcare information technology. This PSO will accept reports regarding clinical healthcare information technology from healthcare providers. The PSO should actively seek reports from clinicians and, within the limits of the 42 CFR Part 3 rules, should make the analysis of these reports part of the council's annual report.

4) Establish within the NCVHS the necessary technical and organizational means to carry out forensic investigations of problems or accidents involving the national clinical healthcare information technology infrastructure. The means should be capable of carrying out immediate, on-site, technical investigation and analysis of events and be available, on-call to the PSO to allow immediate, technically grounded, independent investigation of significant accidents involving the clinical healthcare information technology infrastructure.

To achieve these ends, I recommend that you call on Dr. Peter Neumann of the Stanford Research Institute and Dr. David Woods of The Ohio State University to assist you in establishing the council and setting its initial agenda.

Given the scale and importance of the actions about to be undertaken to create a clinical healthcare information technology infrastructure in the United States it is essential that this type of independent, technically sophisticated and deliberate examination take place.

Sincerely yours,



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