



Federation of American Societies for Experimental Biology

— *Quality Life Through Research* —

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American Society for Pharmacology and
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Research

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March 15, 2010

Ms. Elizabeth Holland
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

VIA ELECTRONIC SUBMISSION TO: <http://www.regulations.gov>

Re: CMS-0033-P

Dear Ms. Holland:

The Federation of American Societies for Experimental Biology (FASEB) welcomes the opportunity to provide comments on the Centers for Medicare and Medicaid Services (CMS) proposed rule on the Electronic Health Record Incentive Program (CMS-0033-P). FASEB is composed of 23 societies with more than 90,000 members, making it the largest coalition of biomedical research associations in the United States. FASEB enhances the ability of scientists and engineers to improve—through their research—the health, well-being and productivity of all people. Our mission is to advance health and welfare by promoting progress and education in biological and biomedical sciences through service to our member societies and collaborative advocacy. As such, FASEB supports the goal of increasing the usage of certified EHR technology by eligible providers and hospitals. Within reasonable guidelines governing patient consent and privacy, the secondary use of electronic health record (EHR) information for biomedical research should be included among the criteria set forth defining meaningful use and governing CMS incentive payments.

Facilitating biomedical research will support the CMS mission to promote quality care for its beneficiaries through medical advancements directly attributable to scientific discovery. For example, the development of more effective therapies for treating Alzheimer's disease, the identification of biomarkers to increase diagnostic accuracy of chronic fatigue syndrome, the improvement of early detection of multiple sclerosis, and the optimization of treatment regimens for stroke victims via comparative effectiveness research are active areas of research that will provide tremendous benefit to patients. Biomedical research continues to address improvement in quality, safety, and efficiency; reduction in health disparities; and improvement in population and public health, all of which are emphasized as specific health outcomes policy priorities in CMS-0033-P, based on the recommendations of the Health Information Technology Policy Committee.

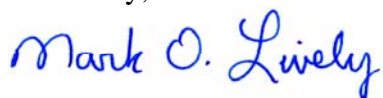
The expansion of the meaningful use definition to include research would allow CMS to leverage an exceptionally rich data source, the collective health

information of millions of CMS beneficiaries, to promote medical breakthroughs. The aggregate health information of the 90 million Americans currently receiving care through Medicare and Medicaid would represent the largest health information data resource in United States history and would arm researchers with unique tools to fight disease and illness. First, the large number of participants would dramatically enhance the statistical ability to detect medically relevant trends and contributions to risk with regard to complex disease. For diseases such as prostate cancer, which affects more than two million American men and is the second leading cause of male cancer death, and for which we know there is a genetic contribution to risk, scientists have struggled to identify the causative or contributing genetic variants. The inclusion of larger numbers of individuals in a study can increase the statistical power to identify contributing genetic and environmental risk factors. Knowledge of specific underlying causal gene mutations can allow for more personalized therapeutic intervention. The identification of high quality candidate participants for clinical trials would also be greatly enhanced by the inclusion of research among meaningful use criteria. Particularly for rare diseases, having patient-consented access to health information from a broad segment of the American public could result in increased participation of affected individuals in biomedical research studies. Similarly, this would facilitate the inclusion of minorities and other groups underrepresented in biomedical and clinical research. In addition, researcher access to patient-consented EHR information would support the real-time post-marketing surveillance of pharmaceuticals and medical devices. Because pharmaceuticals and medical devices are approved on the basis of results of clinical trials among controlled groups of voluntary study participants, they are not always representative of the general population.

In the United Kingdom, as part of its National Health Service (NHS), the Research Capability Programme was created with the primary goal of enabling “research to achieve its full potential as a ‘core’ activity for healthcare, alongside other uses of National Health Service data that lead to improvements in quality, safety, and care.” The UK believes that facilitating research will contribute to improved patient care and public health. Establishing biomedical research as a priority in these early stages of US EHR adoption could add significant value to the CMS health information enterprise and maintain US leadership in biomedical research.

The incentive for EHR adoption and usage represents a golden opportunity to connect clinical care and biomedical research on a national scale and would significantly enhance the ability of scientists to develop new therapeutic treatments that would lead to improved quality of care and better health outcomes. As such, we strongly urge CMS to maximally leverage emerging EHR usage by integrating biomedical research into meaningful use definitions and broader strategic goals. We are grateful to have had the opportunity to share our thoughts on this important issue and look forward to working with CMS to ensure the health and wellness of the citizens of the United States.

Sincerely,



Mark O. Lively, Ph.D.
FASEB President