



#### Former Honorary Chairs

President George H.W. and Barbara Bush

#### Honorary Vice Chair

The Honorable Dianne Feinstein

#### Chair

William Winkenwerder, MBA, MD

Chairman & CEO

The Winkenwerder Company, LLC

Former Assistant Secretary of Defense for Health Affairs, US Department of Defense

#### Vice Chair

Governor Bob Wise

President

Alliance for Excellent Education

#### Treasurer

Cheryl Heaton, DrPH, MPA

President & CEO

LEGACY | For Longer Healthier Lives

#### Secretary

Gary Reedy

Worldwide Vice President

Biopharmaceutical Public Policy

Johnson & Johnson

#### Emeritus Members

LaSalle Leffall, Jr., MD, FACS

Charles R. Drew Professor of Surgery

Howard University Hospital

James Marks, MD, MPH

Senior Vice President & Director, Health

Group

Robert Wood Johnson Foundation

John Seffrin, PhD

Chief Executive Officer

American Cancer Society

#### Board of Directors

Marguerite Donoghue Baxter, RN, MN

Jean Becker

Chief of Staff

Office of President George H.W. Bush

Zora Brown

Special Assistant to the CEO

Integrus Health

Elizabeth Clark, PhD, ACSW, MPH

Executive Director

National Association of Social Workers

Robert Comis, MD

President & Chairman

Coalition of Cancer Cooperative Groups

Gregory Curt, MD

U.S. Medical Science Lead, Emerging

Products

AstraZeneca Pharmaceuticals

Elizabeth Duke, PhD

Senior Lecturer

School of Public Policy

University of Maryland

Lloyd Everson, MD

Chairman, Life Beyond Cancer Foundation

Special Advisor to the CEO, US Oncology-

McKesson

Philip Huang, MD, MPH

Medical Director/Health Authority

Austin/Travis County Health and Human

Services Department

Elmer Huerta, MD, MPH

President & Director, Cancer Preventorium

Prevention, Inc.

Tom Kean, MPH, Ex Officio

Executive Director

C-Change

Stephen Kindred, MD, MPH

Assistance Vice President, Human Resources

State Farm Insurance Companies

Governor Ruth Ann Minner

Former Governor

State of Delaware

Martin Murphy, Jr., PhD, DMedSc

Chief Executive Officer

CEO Roundtable on Cancer

John Niederhuber, MD

EVP, Inova Health System

CEO, Inova Institute for Translational

Research & Personalized Medicine

August 1, 2011

U.S. Department of Health and Human Services

Office for Civil Rights

Attention: HIPAA Privacy Rule Accounting of Disclosures

Hubert H. Humphrey Building

Room 509F

200 Independence Avenue, SW

Washington, DC 20201

## RE: RIN 991-AB62 – HIPAA Privacy Rule Accounting of Disclosures Under the Health Information Technology for Economic and Clinical Health Act (HITECH)

Dear Secretary Sebelius:

C-Change would like to thank the Department of Health and Human Services (HHS) for the opportunity to comment on the notice of proposed rulemaking for the HIPAA Privacy Rule Accounting of Disclosures Under the Health Information Technology for Economic and Clinical Health Act (HITECH).

The mission of C-Change is to eliminate cancer as a major public health problem at the earliest possible time by leveraging the expertise and resources of our members. A 501(c)(3), C-Change is comprised of approximately 150 of the Nation's cancer leaders from the private, public, and non-profit sectors. These leaders collaborate on issues spanning the continuum of research, prevention, and care - *that cannot be solved by one organization or even one sector alone.*

Improving patient privacy protection and reducing impediments to research remains one of C-Change's six strategic priorities. The 2009 Institute of Medicine (IOM) report, [Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health through Research](#), concluded that the HIPAA Privacy Rule does not adequately protect patient privacy and that it significantly impedes research. In the spirit of the IOM report, C-Change aims to change the HIPAA Privacy Rule and related research and health data policies to strengthen patient privacy protection and accelerate cancer research.

With specific regard to this notice of proposed rulemaking, C-Change supports the consideration by HHS to exempt research from the Accounting Requirement. However, C-Change has serious concerns about the proposal for Access Reports and its potential impact on research. We appreciate the opportunity to share our perspective on the potential impact of these issues on patients and research.

1776 Eye Street, NW, 9th Floor, Washington, DC 20006 Tel 202-756-1600  
[www.c-changetogether.org](http://www.c-changetogether.org)

The barriers imposed by HIPAA typically of concern to researchers and the public include selection bias, inefficiency, procedural burdens, and abandoned studies. Translating these barriers into a patient perspective, HIPAA creates obstacles to finding cures for all types of patients; perpetuates health disparities; and delays research into more affordable cures. Revisions must make the patient experience simpler and honor the trust patients impart to researchers by continuing to make experimental treatments available. In addition, the resulting cost burden of these barriers weighs heavily on the healthcare and research system in terms of time, dollars, and the lost opportunity of research no longer feasible because of HIPAA constraints.

C-Change recognizes the important role of health information and health information technology in achieving our Nation's goals to improve patient safety, patient care quality, system efficiency, and ultimately patient outcomes. Similarly, we value the role that information systems play in clinical research and information-based research. In cancer care, clinical research and patient care are inextricably linked. With recent advances made in the understanding of genetic diseases, we stand on the brink of being able to tailor medicines to the specific needs of individual patients. Information-based research is critically important to making strides in personalized medicine targeting more and more refined subpopulations. The HIPAA Privacy Rule, in its current state, poses major barriers to clinical and information-based research as we have stated before in previous public comments to HHS.

C-Change supports the HHS proposal to exempt research disclosures from the Accounting Requirement for reasons related to the adequacy of existing control mechanisms, the potential burden and questionable benefit of continued or new requirements, and consideration for the impact to patients. The patient authorization for research and/or the IRB waiver of authorization contained in existing HIPAA regulations already provides oversight for the appropriate use of patient information for research. Breach notification already provides a mechanism to deter and report inappropriate uses of information. Existing accounting requirements have a minimal impact on improving transparency since patient requests for accounting are so few and the information provided to patients is of questionable utility. Continued or revised requirements would increase the cost and delay the completion of patient oriented research, delaying access and increasing the cost of care. Exemption from accounting requirements promotes comparative effectiveness research, which will allow important discoveries from existing research data to further benefit patients and improve the sustainability of the healthcare system. Lastly, the proposal to exempt research from the accounting of disclosures is consistent with long standing recommendations from The National Committee on Vital and Health Statistics (NCVHS), the Association of American Medical Colleges (AAMC), the HHS Secretary's Advisory Committee on Human Research Protection (SACHRP), and the Institute of Medicine (IOM).

C-Change has serious concerns about the proposal for Access Reports and its potential impact on research. In addition to the points made above regarding existing controls for information within the research process and the questionable utility of this information to patients, the number of information systems used to support the entire spectrum of medical research

activities nationally is so extensive that creating an integrated access report would be extremely complicated, expensive, and disruptive to the research process. Access reports for patients receiving care through clinical trials would be largely duplicative of access reports already created for treatment purposes. Creating additional hurdles for organizations struggling to meet minimal health information technology goals places us farther away from realizing the more important gains in safety and efficacy for patient outcomes and efficiency for a sustainable health system.

As stated in previous comments related to HIPAA in the context of HITECH, the PCAST report, and the National HIT Strategy, our Nation needs a more comprehensive approach to research privacy as recommended in the 2009 IOM report, if it is to rapidly and efficiently realize the health benefits made possible by advances in science and information technology.

Once again, we appreciate the opportunity to comment on this notice of proposed rulemaking. Thank you for considering this input. If we can be of further assistance, please contact Alison Smith, Vice President, Strategic Initiatives [asmith@c-changetogether.org](mailto:asmith@c-changetogether.org) or 708-267-5166.

Sincerely,

A handwritten signature in black ink, appearing to read "Tom Kean", with a long horizontal flourish extending to the right.

Tom Kean, MPH  
Executive Director