June 18, 2013

As health care leaders, we appreciate the Administration’s recognition of the important role that health information technology (IT) plays in improving health and health care and share your view that broad adoption is critical to the success of payment and delivery reforms. We are actively engaged in the transformation of health care from a system burdened by paper to one empowered by interoperable electronic solutions that improve patient safety, reduce the cost and variability of care, and advance health care efficiency and quality. While proper oversight of health IT is critical to ensuring patient safety, such oversight must be implemented in a balanced way that also fosters innovation and encourages adoption of these technologies.

We commend the Administration for recently launching a Workgroup in response to the Food and Drug Administration Safety Innovation Act (FDASIA) of 2012, which calls for the Secretary of Health and Human Services (HHS) to work with the Food and Drug Administration (FDA) Commissioner, the National Coordinator for Health IT, and the Chairman of the Federal Communications Commission (FCC) to post a report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health IT, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication. The thoughtful, comprehensive, and inclusive approach being taken by the Administration to inform Congress will be critical as it develops this new regulatory framework for health IT.

To that end, we urge the Administration to allow ample time for the FDASIA Workgroup to complete its work and to take into consideration the Administration’s final recommendations on a risk-based regulatory framework pertaining to health IT in any future Agency guidance or policy to be released associated with the regulation or oversight of health IT.
We further encourage the Administration to consider any Congressional recommendations on a risk-based regulatory framework that emerge following the publication of the Administration’s final report and to work with Congress on the development of appropriate oversight mechanisms for health IT, including mobile applications. Congress may also choose to pursue revisions to Section 201(h) of The Food, Drug and Cosmetic Act, as amended in 1976, to reflect the explosive growth in and rapidly evolving nature of information technology in health care. We believe that, by working collaboratively, Congress and the Administration can produce a statutory framework for regulation of health IT based on risk while supporting innovation and patient safety.

We look forward to continuing to work with the Administration as well as Congress to ensure that health IT is regulated in a way that achieves the goals of improving the quality, safety and cost-effectiveness of care.

Sincerely,

1DocWay
ABW Medical
Advanced Heart Care
Alliance for Quality Improvement and Patient Safety
ALS Association
American College of Emergency Physicians
American Society of Clinical Oncology
American Association of Diabetes Educators
American College of Physician Executives
American Medical Group Association
American Medical Informatics Association
American Nurses Association
American Osteopathic Association
Ascension Health
Association of Medical Directors of Information Systems
athenahealth
AwarePoint Corporation
AZZLY
BetterFit Technologies
BIO-Key International
Bio-Reference Laboratories, Inc.
Blisstering Solution
Carman Nan, MD
Center for Democracy and Technology
Chaos Health
Coalition of Heritable Disorders of Connective Tissue
June 18, 2013
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College of Health Information Executives (CHIME)
ConversePoint
CPSI
CRG Medical, Inc.
Dell Inc.
DICOM Grid, Inc.
DualAlign LLC
DxID
eCardio
eHealth Technologies
e-MDs
Empower Interactive, Inc.
Entrada
Epion Health
Epocrates
eVariant, Inc.
Evergreen Family Medicine
EW Consulting, Inc.
Eye Center of La Jolla
FlexLife Health
Flor J. Caballar Gonzaga, MD, FAAP
FoodCare Inc.
Frontier Neurosciences
Genelex Corp.
Genetic Alliance
Get Real Health
Greenway Medical
Greenwings Biomedical
Health Care Service Corp.
Healthcare Leadership Council
HealthPost, Inc.
Health Fidelity
HealthFortis
Health Options Worldwide
Hermes Clinical
Hernando County Medical Society
HLM Venture Partners
IMPACTheds
Intel Corporation
InteliChart
Intermountain Healthcare
INUVO, Inc.
Kareo
Keona Health
Leukemia and Lymphoma Society
M3 Information
Madaket Health
Martin, Blanck and Associates
Matrix Partners
McKesson Corporation
MedicalRecords.com
MemorialCare Health System
Metro Atlanta Chamber of Commerce
Microsoft
Modernizing Medicine
Monebo Technologies
MyhealthEcare
National Association of Manufacturers
National Health IT Collaborative for the Underserved
National Patient Safety Foundation
Navigating Cancer
National Retail Federation
NextGxDx
New Capital Partners
New York eHealth Collaborative
Newborn Coalition
Northern Cambria Medical Center
Oracle Corporation
OZ Systems
Patient Conversation Media
Pharmacy e-Health Information Technology Collaborative
pMD
Polyglot Systems, Inc.
Pristine
PXE International
Quality Systems Inc./NextGen Healthcare
QPID, Inc.
Radisphere
RazorInsights
Ringful Health LLC
Seamless Medical
Sharp HealthCare
Siemens Corporation
Silicon Valley Chapter of Health 2.0
Simple Health Ventures Inc.
South Denver Obstetrics and Gynecology PC
StartUp Health
Syapse
Teladoc Inc.
TeleCare Global
Tenacity Health
Texas e-Health Alliance
Tidepool
U.S. Chamber of Commerce
U.S. Oncology Network
UnitedHealth Group
Vieu Health
Visual Health Solutions, Inc.
VitalWare, LLC
WelVU

Copies:
Chris Dawe, Policy Advisor for Healthcare, National Economic Council, Executive Office of the President
Jeanne Lambrew, Deputy Assistant to the President for Health Policy, Office of Health Reform, Office of White House Policy, Executive Office of the President
Todd Park, U.S. Chief Technology Officer and Assistant to the President, Office of the Chief Technology Officer, Office of Science and Technology Policy, Executive Office of the President
Addendum to Letter Dated June 18, 2013
As of June 21, 2013

*Additional Organizations Who Signed on to the Letter After June 18, 2013:*

American Academy of Pediatrics  
ECRI Institute  
Health Level 7 International  
HP  
NexTech  
Suncoast Solutions