

October 7, 2014

Dear Member of Congress:

The undersigned organizations urge Congress to act this year to provide clarity and certainty for appropriate, risk-based oversight of health information technology (IT).

The Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 called upon the Administration to provide recommendations to Congress on an appropriate risk-based framework. With the release of the recommendations in April, it is now time for lawmakers to pass legislation that achieves the complementary goals of protecting patients, ensuring safe and effective care, and fostering continued innovation in the rapidly-growing health IT field.

It is critical that the Senate and House act before the end of the 113th Congress for the following reasons:

1. **Health IT has the potential to greatly improve the efficiency and quality of care delivery.** Health IT helps improve patient safety and healthcare outcomes. Patients and their caregivers use health information software to manage their health and wellness. Wide availability, ease of use, and familiarity with these technologies allow patients and their caregivers to integrate disease management and wellness activities into their daily routines. This technology increases adherence to care plans and reduces preventable hospitalization and associated costs. Health IT enables care providers to access necessary information at the point of care, which can improve the efficiency and quality of care delivery.
2. **Current regulatory uncertainty stifles health care innovation.** Within the broad community of healthcare stakeholders there is near universal agreement that regulatory certainty is essential for continued innovation. We are concerned that there is significant confusion in the market about what technologies may be regulated, by which agencies, and to what standards. This uncertainty creates barriers to the development of promising technologies that can help clinicians access more evidence-based medicine, provide patient populations with specific needs more individualized care, and generate better patient-caregiver-provider engagement. The potential cost and delay created by current regulatory uncertainty may further deter software and system developers from creating products that have the ability to greatly benefit patients.
3. **There is broad consensus on the need for a risk-based framework for health IT.** Members of Congress on a bipartisan, bicameral basis, along with other government officials, including the FDA, together with industry, care providers, patient advocates and other healthcare stakeholders have agreed publicly on the core components of appropriate regulation of health IT. There is broad agreement that: (1) there are three categories of health IT; (2) FDA regulation should continue to be focused on the category of technologies that present a high risk to patient safety; (3) the category of technology presenting no risk to patient safety should remain unregulated; and (4) the third category, encompassing the remainder of health IT that may pose some risk, should be subject to risk-based oversight that uses consensus standards and private certification bodies to verify that these health IT technologies function safely and well.
4. **This is a bipartisan issue that is ready for bipartisan action.** The urgent need for technological modernization of the nation's care delivery system is one of the relatively few health policy imperatives that generates bipartisan and bicameral support. The Administration has identified areas where current

law needs to be updated and additional resources dedicated to improve patient safety. Members of Congress have introduced bills and held multiple hearings on continued innovation in health IT. It is time for modern laws that reflect the technological advancements made in our health care system over the past four decades, and codify a framework that achieves rather than impedes the potential of health IT to protect patients and enhance clinical safety.

Considering the vast potential for improved outcomes, enhanced patient safety, and reduced costs, we hope the Administration and Congress will work together to pass legislation this year to clarify the lines of regulatory jurisdiction by updating the law under which health IT is currently regulated. FDASIA clearly lays out a multi-step process consisting of recommendations by the Administration to Congress (the FDASIA Report), followed by Congressional action, informed by those recommendations, to effectuate changes to ensure an appropriate regulatory framework for health IT.

Before the end of the year, we urge Congress to provide much needed statutory clarity and a stable foundation for continued innovation in health IT. This overdue action will allow the Administration to focus its limited resources, staff and expertise on ensuring the safety of new medical technologies that pose the highest potential risk to patients, and will promote a new era of medical innovation that will improve care and lower costs.

Sincerely,

Access Integrity

Acesis

Alliance for Aging Research

American Association of Diabetes Educators

AMIA

Applied Pathways

athenahealth

Aviacode

Brain Injury Association of America

Business Software Alliance

Center for Data Innovation

ChartRequest

Christus Health

Clockwise.MD

Dicom Grid

Epion Health

Genetic Alliance

GoGoHealth

Health IT Now

Healthfinch

IBM

Ingenious Med, Inc.

Institute for eHealth Policy

Intermedix

International Essential Tremor Foundation

Keona Health

LGBT Technology Partnership & Institute

Maven Medical

McKesson Corporation

Moxe Health
Nalari Health
National Alliance on Mental Illness
National Association of Manufacturers
National Council for Behavioral Health
National Retail Federation
Newborn Coalition
NTCA–The Rural Broadband Association
Open Minds
Oracle Corporation
Ovuline
Parent Project Muscular Dystrophy
Pediatric Hydrocephalus Foundation
PerfectServe
Pharmacy HIT Collaborative
QMedic
Qpid
RetireSafe
Sarcoma Foundation of America
Seratis
Smart Scheduling
Software & Information Industry Association
Suture Health
The Latino Coalition
Trice Imaging, Inc.
U.S. Chamber of Commerce
UltraLinq Healthcare Solutions Inc.
United Spinal Association
US Oncology Network
WellDoc, Inc.
WellTrackONE

cc. Sylvia Mathews Burwell
Secretary, US Department of Health and Human Services