15 October 2014

The Honorable Fred Upton
Chairman, Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515

Request for Comments on Energy and Commerce Digital Health White Paper

Dear Chairman Upton:

On behalf of the American Medical Informatics Association (AMIA), I am pleased to submit these comments in response to the above-referenced request for comments. AMIA is the professional home for over 5,000 members who are focused on biomedical and health informatics and who work throughout the health system in a broad spectrum of clinical care, research, academic, government, and commercial organizations. AMIA is dedicated to the development and application of informatics in support of patient care, public health, population health, consumer health, professional development, research, and administration. We also seek to advance the development of effective policies and regulations to support our members and mission. AMIA ultimately works to enhance human health and health care delivery through the transformative use of information and communications technology.

To facilitate the discovery, development and delivery of new treatments and cures, AMIA believes that we must develop a "learning health system" in which the data and information generated during routine delivery of health care is leveraged across clinics, hospitals and integrated networks for a wide variety of legitimate and positive purposes, including but not limited to health professional education, quality improvement, evidence-based practice, research, and evaluation of programs as well as policies.

AMIA commends the Energy and Commerce Committee for launching the 21st-Century Cures Initiative and for seeking stakeholder input on the topic of digital health care. We agree with the Committee that digital health care holds tremendous promise and will play a key role in advancing innovation that can bring new medical therapies to patients more efficiently. Widespread adoption of health information technology and a boom in the digital health space has redefined the way we deliver care both inside and out of clinical settings. Technologies that generate and disseminate data now exist in every aspect of consumers' daily lives and health care is no exception. Increasingly, devices and applications are enabling both patients and providers to have new means of interacting with one another. Innovation in this space is fueling new methods of care delivery, including redefining the point of care from the traditional clinical setting to a person's current location. As the digital health landscape continues to evolve, it is important that federal policies maintain an appropriate balance between allowing for innovation and protecting patient and caregiver interests.

In this comment, AMIA outlines suggested recommendations for Congress to take that will promote increased data sharing, ensure the security of patient data, and support a well-trained workforce to maximize the potential of digital health.

<u>**Comments in Response to Questions Outlined by the Committee:**</u>

In seeking to promote innovation across the health care continuum, the power of data must be used to maximize its potential to transform medical discovery and care delivery. Increased data sharing among patients, caregivers and providers can facilitate better care; those same data, made available through appropriate means and with adequate protections for individuals, can promote new research and discovery, identify opportunities for care optimization, and facilitate innovation and the creation of novel medical interventions. In your white paper, you ask what barriers prevent these technologies from being used on a larger scale and what can Congress do to address them? Below are AMIA's recommendations for addressing barriers to improving data sharing and for changes to HIPAA that would improve research access to data while ensuring the privacy and security of patients' personal health information.

<u>**Improve Research Access To Health Data To Benefit Patients:**</u>

1. **Consider amending HIPAA to define data research as part of health care operations (at § 45 CFR 164.501 and 164.506)**
   In defining the <u>routine activities</u> (of treatment, payment and health care operations – otherwise known as TPO) for which covered entities (doctors, hospitals, other providers; health plans and payers; etc. – otherwise known as CEs) may use protected health information (PHI) without obtaining a specific consent of the individual, HIPAA did not include observational or data **research** as a *health care operation*, yet such "non-interventional" research (e.g., research utilizing already collected data which does not require patients taking a drug or providing a new blood sample) is essential for the discovery, development and delivery of new treatments and new cures.

   In defining *health care operation* activities that a hospital or other CE can undertake, such as quality assessment and improvement, outcomes evaluation, and the like, HIPAA indicates that the use of PHI without specific consent is permitted <u>only if</u> "the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities." In effect, HIPAA establishes a strong disincentive <u>against</u> the use of health data to pursue "generalizable knowledge," that is, for research. Most hospitals and medical practices (and other CEs) believe then that health data can be used only for studies relating to their own institution or organization, and that they cannot allow the use of "their" PHI for research purposes, absent a specific consent (HIPAA authorization) from each individual patient. As a result, vast troves of clinical (e.g., electronic health records and administrative records) and high-volume molecular (e.g., genomic data and biomarkers) data are effectively siloed within thousands of health care facilities and organizations and not used (or "mined") by either CEs or their business associates (BAs) conducting research activities on the CEs' behalf for research that could contribute to the discovery, development and delivery of new treatments and cures.

   In fact, HIPAA provides considerable latitude for research uses (and disclosures) of PHI, but CEs (and their Institutional Review Boards or IRBs) vary widely in their interpretation of HIPAA and often fail to adequately understand and utilize HIPAA provisions that permit approval of a *waiver of authorization*, the use of *limited data sets*, and *de-identification* of PHI for research purposes. Under-resourced IRBs often lack expertise in privacy and data security and many are ill suited to assess the "risk" to patient privacy posed by data-driven research, including research using large data sets.

   AMIA's recommendation:

- Congress should consider amending the HIPAA definition of health care operations to have it include "non-interventional research " as an appropriate operational use of PHI would send a clear message to CEs, BAs, IRBs, regulators and others, including patients, that utilizing the promise of health data is, in fact, a core responsibility of all the stakeholders in the health care system. Simply, we trust CEs (and their BAs) to use the health data of individuals for the purposes of treatment and payment and health care operations that facilitate their own functioning – we ought to trust them as well with the responsibility of conducting research with health data to improve the health of our nation as a whole.

2. **Convene a Multi-Stakeholder "HIPAA Barriers" Working Group**
Many HIPAA-era problems relating to timely access to health information reported by health system stakeholders – including patients, providers, educators, clergy, law enforcement and others –have resulted from confusing, inconsistent and generally inadequate guidance from HHS agencies that has not kept pace with the dramatic advances in information and communication technologies. In part this is understandable, since the DHHS Office for Civil Rights is charged to focus on privacy considerations and other requirements of HIPAA and not upon how best to assure privacy within the context of meeting other legitimate societal interests.

    AMIA's recommendation:
    - Congress should direct the Secretary of HHS to convene a multi-stakeholder "HIPAA Barriers" Working Group with a mandate to surface issues of impeded data movement within the health care system and to propose a plan for addressing the timely and efficient use of health information for research, while also addressing the confidentiality, security, and privacy of individuals. The working group should include patients and caregivers who have experienced challenges in accessing their own personal health information.

3. **Assure Public Transparency on Responsible Research Data Uses and Reporting of Breaches**
With the responsibility to conduct research on behalf of patients as a whole comes the parallel responsibility to protect the privacy and security of the data pertaining to them. Researchers whose activities occur under a CE, or as a BA working on behalf of a CE, are subject to the HIPAA breach reporting requirements of 45 CFR § 164.400, whether or not the definition of *health care operations* is amended to include research. Public trust will also improve as patients (and their caregivers) have a clearer understanding of how their PHI is used to support research – including its inclusion in de-identified or anonymized data repositories.

    AMIA's recommendation:
    - In order to build public trust in the research enterprise (which has never, to our knowledge, suffered a meaningful breach of a research data set), Congress should direct the Secretary of the Department of Health and Human Services (HHS) to prepare a report annually that would address such topics as: an estimate of the number of research projects accessing PHI under an amended definition of health care operations; an analysis of any misuses or other problems observed with newly permitted researcher access to PHI; a report of the number of data breaches occurring pursuant to such newly permitted researcher access to PHI; an analysis of existing methods that prove effective for reducing opportunities for data breach or misuse; and such other topics as Congress may suggest.
    - If Congress agrees that a modification of the HIPAA definition of healthcare operations to include "non-interventional research" is warranted (as discussed in topic 1 above), a balancing methodology for creating transparency around these secondary uses of data should be considered as well. Congress should consider requiring covered research groups

to produce a publicly available annual report detailing the sources, uses, and destinations of all PHI that was touched.

4. **Ensure the Safe Use of Electronic Health Records and Other Health Information Technologies**

In your white paper, you ask stakeholders how Congress can ensure innovation of new medical technologies, such as mobile medical applications, while mitigating the risks to privacy and security that can stem from their integration into the health care system. As with nearly every other aspect of our lives, health care will continue to shift away from centrally managed data (i.e., the electronic health record) and into a more complex and vibrant ecosystem of tools, mobile devices, data repositories, analytics engines and other technologies that create opportunities for better care while posing new risks and challenges. With patients having more information today than ever before, investments are required in assuring that patients have the tools and understanding necessary to engage successfully in their health care. Unintended consequences can arise due to a number of problems within our health IT systems, causing inefficient care, data loss, and in rare cases patient harm. Therefore, it is critical that we develop a shared understanding of those problems and their potential remedies.

In the recent FDASIA HIT report[1] released by FDA, FCC, and ONC, a recommendation was put forth for the creation of an HIT Safety Center. We believe that the Health IT Safety Center as imagined in the report – a convener of stakeholders rather than an additional regulatory body – is an effective approach to promoting patient safety. Innovation in the health IT sector plays an integral part in advancing new patient therapies and treatment options and in the sharing of data across the health care delivery system. We also agree with the report that the Health IT Safety Center should not play a direct role in regulation, but rather should serve as a source of data, research, and best practices for the safe use of HIT. Having a central convener for these important discussions will improve awareness of total cost of regulatory compliance; this awareness can contribute to a more streamlined approach to safety reporting.

Through the creation of a single body focused on health IT safety – the Health IT Safety Center – we believe that event reporting, education, data aggregation, and the creation of best practices can improve patient safety and the effective use of health IT. We believe the operating principles for an HIT Safety Center should include:
  ● A system of IT safety reporting that is non-punitive and includes liability protections
  ● A system for the reporting of "near-misses" – as well as actual errors – including errors in both software design and use as well as care delivery errors
  ● A well-defined system of feedback to users of health information technologies

AMIA's Recommendation:
  ● Congress should support the creation of the Health IT Safety Center as envisioned in the FDASIA report through appropriations and through the explicit empowerment of the Office of the National Coordinator for HIT (ONC) to create such a public-private partnership entity in the event that Congress finds that such explicit empowerment is warranted.

5. **Continue support for Biomedical and Health Informatics Workforce Training and Education:**
    As the digital health landscape continues to evolve, the need for a well-trained and competent workforce of health professionals and biomedical researchers is growing exponentially in its

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[1]http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM391521.pdf

importance. Trained professionals are essential to optimizing patient care and our overall health through the advancement of the knowledge, discovery, and innovation needed to improve the quality and safety of health care, improve population health, and reduce costs.

AMIA's recommendation:
- Congress should continue to fund informatics training programs run by the National Library of Medicine as part of a broader effort to engage health care professionals and consumers at every skill level in the effective use of electronic data sources and health information technology. These programs train the scientific community in challenging areas that include organizing, analyzing, and integrating datasets composed of phenotypic, molecular, exposure, and other types of data that require specialized training.

AMIA appreciates the opportunity to submit these comments to the Energy and Commerce Committee. AMIA commends the Committee for their launch of the 21st-Century Cures initiative and hopes that engagement with stakeholders across the health care landscape will lead to improvements in the digital health sector and across the health care landscape for the ultimate benefit of patients, caregivers and our citizenry as a whole.

Sincerely yours,

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CC:
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