

July 1, 2014

The Honorable Fred Upton  
Chairman, Committee on Energy and Commerce  
U.S. House of Representatives  
2125 Rayburn House Office Building  
Washington, DC 20515

The Honorable Diana DeGette  
U.S. House of Representatives  
2368 Rayburn House Office Building  
Washington, DC 20515

Dear Chairman Upton and Congresswoman DeGette:

vitaTrackr is pleased to provide comments on the 21<sup>st</sup> Century Cures Initiative: A Call to Action – Digital Health Care white paper.

We applaud your efforts and support the need to transform the health industry to a 21<sup>st</sup> century level of efficiency. Every day, in nearly all aspects of life, we benefit from revolutionary information technology and data management. Yet in the most data intensive industry where data can be the difference between life and death, somehow we remain generations behind in reaping the rewards of information technology.

Phil Fasano, Executive Vice President and Chief Information Officer of Kaiser Permanente summed up the situation in healthcare quite viscerally in his 2013 book Transforming Healthcare the Financial Impact of Technology, Electronic Tools and Data Mining, “In 1969, just six weeks after NASA landed the first men on the moon, the first \$20 bill was dispensed from an automated teller machine. IT systems have since revolutionized financial services, and as a result banks have since saved billions of dollars...from my perspective, healthcare IT is still just a few paces beyond where the financial services industry was in 1969”

### **Focus of vitaTrackr Comments**

Thus far comments submitted to the Committee focus on specific recommendations relative to the application of data in healthcare. There is little doubt as to the massive implications of digital health care, vitaTrackr’s comments focus on how to achieve “digital health” – ***specifically how can the industry break through legacy barriers of sharing health data across the industry to all points where/when necessary as it is needed to optimize care and outcomes, enhance research, engage consumers and perform at a level of efficiency that yields a health system that our Nation can afford.***

The health industry data challenge has raged for decades now. As Mr. Fasano states, other industries have been revolutionized while healthcare languishes. It is not for a lack of focus and effort. Over the decades since the dawn of the information age, enormous attention, resources and countless dollars have been expended to address the health data challenge.

Much of the focus (and debate) centers on several core issues: funding, standards, technology and interoperability.

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<sup>1</sup> Fasano, Philip. *Transforming Health Care: The Financial Impact of Technology, Electronic Tools, and Data Mining*. Hoboken: John Wiley & Sons, 2013. Print.

## **vitaTrackr Point of View**

vitaTrackr was established with a point of view that the challenge of moving data in healthcare has ***nothing to do with any of these issues***, certainly not funding. vitaTrackr's premise is simple: the barrier to moving data in healthcare is ***a market issue***.

## **Health Industry Evolution – a vitaTrackr Perspective**

Healthcare has evolved from its roots as a “local business”. Local doctors, clinical support and facilities have addressed virtually every health need within a community. For generations, this model worked well. With the dawn of the information age almost forty years ago this foundation uncovered what has become a near fatal flaw. The need to share information across geography and market sectors was virtually non-existent during this period in healthcare.

As information technology established an early presence in the industry the focus was data automation within an organization – be it a health system, a health insurance provider or any other health silo. The IT industry rushed to the rescue of these organizations by deploying customized platforms in response to the specific structure of an organization and the direction provided by each organization's planners. We continue to live with this legacy – a lack of interoperability.

As information technology continued to advance a new challenge emerged – “data” evolved to become a competitive factor - the larger the institution the greater the data repositories, the greater the competitive advantage. Sharing data may be positioned as a challenge under the mask of technology and standards, but at its core it is a marketplace behavior that prevents the wide open movement of data across the industry.

Against this backdrop the relentless evolution of information technology accelerated impacting all facets of the economy and society. Within healthcare information technology based capabilities have flourished - genomics, data analytics, a constant stream of evolving data sources, technologies and platforms, as well as new channels of care – retail, urgent care, health management capabilities, gamification – the list is endless. But as the list grows, the underlying structure of healthcare is further stressed to support these innovations.

Unique industry complications also arise providing further challenges: the question of “whose data is it” – the institution or the consumer upon which any data element was created? Data privacy, identified and de-identified data as examples.

## **Core Industry Challenges:**

1. How can the competitive motivation in healthcare transition from rewarding “data islands” to rewarding “connected health”?
2. How can an industry as diverse as healthcare coalesce around a solution that benefits everyone, but does not uniquely advantage “anyone”?
3. How does the ultimate data “owner” the consumer, recognize the benefits of data management while retaining control over the use of their personal health data?

## **vitaTrackr Health Data Marketplace**

vitaTrackr is a health data marketplace. It connects health data sources with data destinations and intermediates consumer consent as necessary. (Sources are defined as “suppliers” or “sellers”; destinations – “consumers” or “buyers”.) Sources create data; destinations utilize data. vitaTrackr is an independent agnostic utility supporting the health industry's data transfer needs. By design, vitaTrackr does not create data, analyze it or add value to it. Those functions are the domain of the marketplace participants. vitaTrackr is an industry enabler.

**vitaTrackr Marketplace functions:**

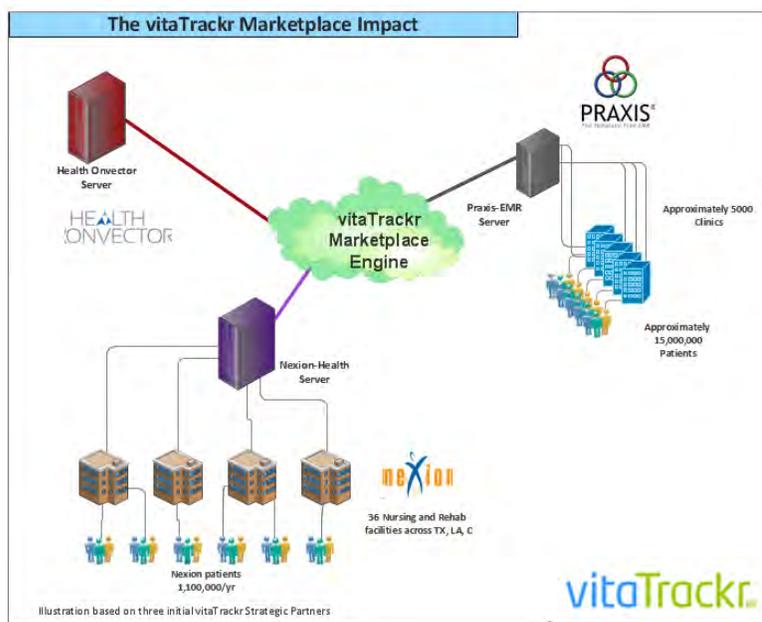
1. **Data transformation** – transforming source inputs to destination requirements;
2. **Consumer authorization** –vitraTrackr intermediates consumer authorization to transfer data from source to destination. vitaTrackr supports two levels of consumer authorization: direct and indirect. Direct is an explicit authorization from a consumer to transfer their data to a specified third party. Indirect is authorization granted through existing relationships, e.g. physician/patient;
3. **Consumer mapping** – aligning consumer identification on both sides of the data transaction;
4. **Data transfer** – vitaTrackr does not persist identified data, it completes the connection between parties, passes the data, receives a handshake confirmation the data was received in a usable format and immediately releases all identified data.
5. **Financial settlement** – sources define their data pricing plan; vitaTrackr settles transactions between buyer and seller.

**An operating example:**

On May 29, 2014, vitaTrackr issued a press release announcing several strategic partners that provided an illustration of the implications and opportunities associated with an open health data marketplace. The press release is attached, but excerpts are provided below to highlight the perspective of three vitaTrackr strategic partners: Praxis EMR, Health Onvector and Nexion Health.

**Praxis-EMR**

- **What:** #1 rated EMR system in use in more than 5000 clinics across all 50 states connected to more than 15mm patients.
- **Challenge:** integrate patient treatment data that may occur outside of physician practice; encourage patient use of EMR data; keep physicians current with clinical innovations.
- **vitaTrackr advantage:** interexchange of patient data between primary care and alternate care settings, e.g., Nexion Health – rehab; access new diagnostics testing results, e.g., Health Onvector; addition of Health Onvector blood viscosity test and treatment – applications, results and protocol to Praxis Knowledge Exchanger.



**Dr. Richard Low, founder and CEO of Praxis:** "Physicians are increasingly frustrated with the breakdown in the promise of electronic health records. The physician disappointment exists because it is still nearly impossible for data to be shared across the industry to provide "best" care for patients. When we first heard of vitaTrackr, its proposition of neutral data, easy access and distribution across the industry, it represented the link that our clients are looking for. This will allow us to focus on continuing to advance our platform, while the issue of industry-wide data movement is addressed by the vitaTrackr utility."

## Health Onvector

- **What:** world-leading technology in blood viscosity measurement, analysis and treatment. Focused on cardiovascular health – reduce mortality and cost of care; extend life, improve quality of life for mid-life adults and seniors.
- **Challenge:** assimilating new diagnostic test into mainstream healthcare market; transferring diagnostic results and treatment plan to client's primary care physician.
- **vitaTrackr advantage:** access to 5000 Praxis-EMR clinics and their 15,000,000 associated patients.

**Daniel J. Cho, Director and CEO of Health Onvector:** "Health Onvector is focused on enabling dramatic improvements in cardiovascular health by developing innovative diagnostic measures like blood viscosity. Statins and other cardiovascular medications already lower blood viscosity levels for millions of Americans, but viscosity is not yet widely measured to monitor and guide these therapies. Unfortunately, in today's current healthcare environment it can take a decade or more for a diagnostic innovation to advance throughout mainstream medicine. By connecting to the vitaTrackr marketplace, we will be linking with more than 5,000 clinics and millions of potential patients."

## Nexion Health

- **What:** nursing and rehabilitation; 36 locations across Texas, Louisiana and Colorado; supports 1.2mm patients per year.
- **Challenge:** transferring treatment data to patient's primary care; receiving data from primary care in the event of a subsequent admit.
- **vitaTrackr advantage:** any patients supported by a physician with a Praxis EMR can easily exchange data bi-directionally.

**Fran P. Kirley, founder and CEO of Nexion Health:** "Physical rehab is an ongoing effort. Progress is made, patients are released back to their day-to-day world, however in some cases they relapse. Our challenge is sharing data back and forth with a patient's primary care network. If a patient relapses and they return to us, we have no idea what subsequent treatment they've received. We lose time and efficiency and the patient is inconvenienced. vitaTrackr offers us the potential to connect some of our million plus patients back to their primary care providers to ensure we have the right data to best treat their needs."

Prior to their participation in the vitaTrackr marketplace, these three organizations had no knowledge of each other, and no logical means of connecting. By participating in the marketplace they will be connected and enabled to share health data in the support of care as well as accelerate innovative diagnostic and treatment innovations quickly and easily across a large base of physicians and patients. The next EHR vendor that connects to the marketplace will immediately expand the connectivity of Nexion and Health Onvector; the next device or diagnostic test is connected and thus the cycle begins where competitive advantage accrues to the "connected organization".

The evolution of our technology intensive society no longer conveniently maps to local communities. Nexion operates in three states, Praxis has clinic customers in all fifty states and Health Onvector is currently a private pay diagnostic service offered through a network of participating physicians and labs.

Personal health monitoring devices, alternate points of care – retail/urgent care, travel patterns all dictate the need to manage the flow of data at an industry-wide level as opposed to community-wide. Focusing on community based connectivity limits the efficiency gains, frustrates and confuses consumers due to the lack of consistent service/experience from community to community and perpetuates the fragmented nature of the industry.

A simple new consumer focused health monitoring device sold direct to consumers across the country, or a new diagnostic testing capability – absent a connected marketplace is virtually impossible to connect the data flow from the device or test into the multitude of physician practices, EHR platforms, HIEs, ACOs,

health systems, new mobile applications, health management services, research efforts that could benefit from a new data source.

As the Committee undertakes the 21<sup>st</sup> Century Cure initiative in 2014, it operates within a “known environment” of health data generating products/services and apps. By 2015 that list of “known sources” will be obsolete as new products, services and apps are introduced to the industry. It is essential that the Committee address the challenge of data movement in a dynamic means that will accommodate innovations that enter the industry and may not yet even be on a drawing board.

The vitaTrackr proposition – “one connection – data distribution across the industry where/when it is needed as authorized by the consumer.”

### **Why vitaTrackr**

vitaTrackr enables the utilization of data in ways that we can only imagine today. It enables the “network effect” in health data. Each additional data source increases the overall value of the marketplace; each additional data user attracts more sources, etc. It utilizes market force to drive data sharing. Any entity that chooses to limit their product or service to data they directly control will ultimately be competitively disadvantaged. Data access is no longer a competitive advantage, but “data optimization” is essential to surviving and thriving in a data-based era of healthcare.

### **Neutrality is Key**

Any individual entity or even industry sector effort to address this challenge will always be suspect in the market given their core business focus and competitive conflicts. Efforts like Microsoft HealthVault, Google Health are instantly encumbered by their core business focus and their competitive positioning in the market. Facilitating the movement of health data is not a “side-business” pursuit. The mission and focus must be singularly oriented so that consumer needs as well as those by every other industry segment are represented.

Even with some of the most recent announcements by Google, Apple, Samsung and others entering the health industry with new devices, consumer experiences and offers to aggregate patient data, already questions are arising as to the interoperability of these platforms. Further questions will arise at the clinical level – should a connection be made with the Google platform, the Apple platform, the Samsung platform – all of them? Each additional one that enters the market? Will user data authorizations pass from one platform to another?

Sector based efforts are also challenged to maintain neutrality and independence. As an illustration:

- On March 4, 2013 the CommonWell Health Alliance was launched with the following vision, (per their website):

The CommonWell Health Alliance is an independent, not-for-profit trade organization open to all health information technology suppliers devoted to the simple vision that a (SP) health data should be available to individuals and providers regardless of where care occurs. Additionally, provider access to this data must be built-in health IT at a reasonable cost for use by a broad range of healthcare providers and the people they serve.

One year later, on February 24, 2014, Carequality was launched with the following vision, (per their website):

- Carequality is an industry-driven collaborative that will facilitate industry consensus and develop and maintain a common interoperability framework, focused on the essential elements needed for networks to interconnect and exchange data between and among networks.

While both of these efforts are positive steps toward interoperability, neither provides a tangible, functional and operational solution. Industry consensus is a laudable goal, but it is not actionable. Standards alone do not drive market behaviors. They do not provide the market force that will launch the next generation of healthcare.

These efforts also fail to address other questions such as: is the management of individual health information a clinical or consumer function? If it is clinical – which physician or institution bears responsibility for aggregating and managing all clinical and non-clinical patient data? (Do physicians even want this responsibility?) If it is the consumer's responsibility what convenient, consistent, easily accessible and uniformly available solution is envisioned to enable consumer consent to pass data?

### **Independence is key; inclusion is essential**

While the independence of the vitaTrackr marketplace is key, vitaTrackr recognizes industry inclusion is essential for the adoption and utilization of its data marketplace. Therefore, vitaTrackr has taken a unique approach to establishing its marketplace. Ten industry sectors have been identified as beneficiaries and initial participants in the vitaTrackr marketplace:

- Health Providers
- Health Insurance
- Pharmaceutical
- Medical Device
- Health Management
- Electronic Health Record
- Labs
- Life Insurance
- Pharmacy Benefit Management
- Retail – Pharmacy

vitaTrackr has reached out to seventy six industry leading companies across these sectors. (Initial invitation cover letters attached). The proposition – the challenge of moving health data is not a sector issue and it is not a company/organization issue – it is an industry-wide challenge which requires industry-wide collaboration to address. The solution is one that in the words of John F. Kennedy – “a rising tide lifts all boats” has perhaps never been more appropriate. The solution will advance the entire health industry and create an environment where industry participants no longer compete on access to data, but the value they add to it.

vitaTrackr has invited two representatives from each of these industry sectors to participate in bringing the marketplace to market. Each participating company will have an ownership stake in vitaTrackr, will represent their respective sector in the final design of the marketplace and participate in its evolution to ensure that the unique needs of their sector are represented. The initial participants will also serve to jump-start the marketplace by participating as data sources and/or destinations.

While the composition of companies that bring vitaTrackr to market is being finalized, the implications of an open marketplace are irreversible. Once set in motion – organizations can choose to “connect” or remain a data island, at their peril.

### **A proven model**

The vitaTrackr approach is based on proven models from other industries. While examples exist in different industries, the Visa model (and the credit card industry at large) provides a basis of comparison. Visa is neither a bank nor a credit card issuer. It manages a network that connects 2.2 billion cardholders to 36 million merchants across 15 thousand financial institutions and processes 13 thousand transactions per second. Visa has been referred to as “a corporation whose product is coordination.” Dee Hock, the creator of the Visa network referred to it as an “enabler”.

Healthcare is at a cross roads, continue down a path of competing on data, or level the data playing field and enable every entity in the industry to focus on creating the absolute best (data-enabled) product, service, application, research effort or consumer experience possible. vitaTrackr – is an enabler.

### **Summary**

vitaTrackr represents a unified effort across a broad cross section of industries and companies collaborating to address a major challenge facing our Nation – the unsustainable cost of healthcare. Rather than a federally controlled, (tax-dependent) solution, vitaTrackr is a private industry, financially self-sufficient, independent solution that benefits all, while advantaging no one sector or entity. Every company and sector will benefit, but the consumer will be the ultimate beneficiary as healthcare becomes more affordable, more easily accessed and with the potential of data-enriched research, ever more effective.

Respectfully,



Brian J Baum  
Founder/CEO vitaTrackr

cc: Dr. Richard Low – Founder/CEO PraxisEMR  
Daniel J. Cho – Director and CEO Health Onvector  
Fran P. Kirley – Co-founder and CEO Nexion Health

### Attachments:

- vitaTrackr – May 29, 2014 Press Release
- vitaTrackr invitation list to companies representing nine market sectors
- vitaTrackr follow up invitation to ten life insurance sector companies

**FOR IMMEDIATE RELEASE:****vitaTrackr Connects To More Than 16 Million Patients/Consumers After First 30 Days of Strategic Partner Program**

BALTIMORE, May 29, 2014 - vitaTrackr, Inc., the global leader in organizing an independent and agnostic health data market today announced it had crossed the 16 million threshold for consumers connected to its marketplace.

Brian Baum, founder and CEO of vitaTrackr said, "This milestone exceeds our expectations. While the value of leveraging health data in the delivery, innovation and efficiency of care seems obvious, the fact that so many organizations have responded this quickly underscores the excitement and potential for the future of healthcare."

vitaTrackr is a health data marketplace connecting data sources with destinations. It transforms data between disparate parties and intermediates consumer authorization where necessary. vitaTrackr is a neutral industry-wide data utility agnostic to source and destination. Baum added, "The value of vitaTrackr is best told through its partners."

**Praxis EMR** – a number one ranked electronic health record provider used by more than 5,000 clinics across all 50 states. Dr. Richard Low, founder and CEO of Praxis said, "Physicians are increasingly frustrated with the breakdown in the promise of electronic health records. The physician disappointment exists because it is still nearly impossible for data to be shared across the industry to provide "best" care for patients. When we first heard of vitaTrackr, its proposition of neutral data, easy access and distribution across the industry, it represented the link that our clients are looking for. This will allow us to focus on continuing to advance our platform, while the issue of industry-wide data movement is addressed by the vitaTrackr utility."

**Nexion** – a network of nursing and rehabilitation centers with 36 locations across Texas, Louisiana and Colorado. Fran Kirley, founder and CEO of Nexion said, "Physical rehab is an ongoing effort. Progress is made, patients are released back to their day-to-day world, however in some cases they relapse. Our challenge is sharing data back and forth with a patient's primary care network. If a patient relapses and they return to us, we have no idea what subsequent treatment they've received. We lose time and efficiency and the patient is inconvenienced. vitaTrackr offers us the potential to connect some of our million plus patients back to their primary care providers to ensure we have the right data to best treat their needs."

**Health Onvector** – developer of a patented blood viscosity measurement, analysis and treatment technology. Daniel Cho, co-founder and CEO of Health Onvector said, "We are focused on enabling dramatic improvements in cardiovascular health by developing innovative diagnostic measures like blood viscosity. Statins and other cardiovascular medications already lower blood viscosity levels for millions of Americans, but viscosity is not yet widely measured to monitor and guide these therapies. Unfortunately, in today's current healthcare environment it can take a decade or more for a diagnostic innovation to advance throughout mainstream medicine. By connecting to the vitaTrackr marketplace, we will be linking with more than 5,000 clinics and millions of potential patients."

Baum added, "We launched vitaTrackr with the belief that in today's data enabled world, the healthcare industry has not embraced nor recognized the full benefit of technology. Given the legacy of the industry as a local / regional business, all too often "data" is leveraged as a competitive asset rather than an enabler. The industry goal must be first – best medicine; everything else flows from there."

Beyond these examples vitaTrackr is currently in conversations with healthcare companies large and small, established and early stage. Baum said, “The potential is both exciting and frustrating. vitaTrackr’s mission is to make access to and use of health data neutral. We free up companies and innovators to focus on “healthcare”, not the challenge of accessing health data.”

visit [www.vitaTrackr.com](http://www.vitaTrackr.com).

Also, join the conversation [www.healthdataneutrality.com](http://www.healthdataneutrality.com)

### **About vitaTrackr.**

vitaTrackr is a health data marketplace that facilitates the movement of health data from the point at which it is created to qualified destinations that value it. vitaTrackr is an industry-wide utility that benefits all, but advantages no individual sector or entity. The consumer, (data owner) will directly authorize data transfers.

### **Contacts:**

#### **vitaTrackr**

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CEO, vitaTrackr, Inc.

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#### **Praxis Electronic Medical Records**

Oliver Peter Hager

[www.praxisemr.com](http://www.praxisemr.com)

#### **Nexion Health**

Fran P. Kirley  
President & CEO

[www.nexion-health.com](http://www.nexion-health.com)

#### **Health Onvector**

Daniel J. Cho  
CEO and Director

[www.healthonvector.com](http://www.healthonvector.com)

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March 7, 2014

**ATTACHMENT 1:**  
vitaTrackr marketplace invitation initial list of invited companies  
21<sup>st</sup> Century Cures: A Call to Action – Digital Health

# It Is Time To Stop Talking About Moving Data In Healthcare

**We are forming a 20-member consortium that will build the health data market.**

*A unique challenge, a unique invitation:*

**HEALTH PROVIDERS**

Delos M. Cosgrove, MD  
**Cleveland Clinic**  
Paul B. Rothman, MD  
**Johns Hopkins Medicine**  
John H. Noseworthy, MD  
**Mayo Clinic**  
David Torchiana, MD  
**Massachusetts General**  
Dean M. Harrison  
**Northwestern Memorial**  
Steven J. Corwin, MD  
**New York Presbyterian**  
David T. Feinberg, MD  
**UCLA Health**  
Mark R. Laret  
**UCSF Medical Center**  
Elizabeth Nabel, MD  
**Brigham and Women's**  
Jeffrey A. Romoff  
**UPMC**

**EMR SYSTEMS**

Jonathan Bush  
**AthenaHealth**  
Paul Black  
**Allscripts**  
Neal Patterson  
**Cerner**  
Judith R. Faulkner  
**Epic Systems**  
John Dineen  
**GE Healthcare**  
Wyche T. Green III  
**Greenway**  
John H. Hammergren  
**McKesson**  
Gregory Sorensen, MD  
**Siemens Healthcare**

**MEDICAL DEVICE**

Miles D. White  
**Abbott**  
Vincent A. Forlenza  
**Becton Dickinson**  
Michael F. Mahoney  
**Boston Scientific**  
Bryan C. Hanson  
**Covidien**  
John Dineen  
**GE Healthcare**  
Alex Gorsky  
**Johnson & Johnson**  
Omar S. Ishrak  
**Medtronic**  
Deborah DiSanzo  
**Phillips Healthcare**  
Jack Phillips  
**Roche Diagnostics**  
Kevin A. Lobo  
**Stryker**

**RETAIL – PHARMACY**

Larry J. Merlo  
**CVS Caremark**  
Rodney McMullen  
**The Kroger Company**  
John T. Standley  
**RiteAid**  
Robert L. Edwards  
**Safeway**  
Gregg W. Steinhafel  
**Target**  
Gregory D. Wasson  
**The Walgreen Company**  
C. Douglas Mcmillon  
**Walmart**

**PHARMACEUTICAL**

Richard A. Gonzalez  
**Abbvie**  
Paul Hudson  
**Astrazeneka**  
Ian T. Clark  
**Genentech**  
Deidre P. Connelly  
**GlaxoSmithKline**  
John C. Lechleiter  
**Lilly**  
Kenneth C. Frazier  
**Merck**  
Andre Wyss  
**Novartis**  
Ian Read  
**Pfizer**  
Anne Whitaker  
**Sanofi**

**HEALTH MANAGEMENT**

Richard Noffsinger  
**Active Health**  
Ron Zwanziger  
**Alere**  
George DeVries  
**American Specialty Health**  
Jerry Vaccaro  
**APS Healthcare**  
Ben R. Leedle, Jr  
**Healthways**  
Larry Renfro  
**OPTUM**  
Judy Smythe  
**WebMD Health Services**

**HEALTH PLANS**

Mark T. Bertolini  
**Aetna**  
Scott Serota  
**BCBSA**  
David Cordani  
**Cigna**  
Frank J. Branchini  
**Emblem Health**  
Bruce D. Broussard, MD  
**Humana**  
Bernard Tyson  
**Kaiser Permanente**  
Stephen J. Hemsley  
**UnitedHealth Group**  
Joseph R. Swedish  
**Wellpoint**

**PHARMACY BENEFIT  
MANAGEMENT**

Mark Thierer  
**Catamaran Corp**  
Larry J. Merlo  
**CVS Caremark**  
George Paz  
**Express Scripts**  
Dirk McMahon  
**OPTUMRx**  
Eric Elliott  
**Prime Therapeutics**

**LABS**

David P. King  
**Labcorp**  
Stephen H. Rusckowski  
**Quest Diagnostics**

**ATTACHMENT 2:**  
vitaTrackr marketplace invitation Life Insurance sector marketplace  
21<sup>st</sup> Century Cures: A Call to Action – Digital Health

April 17, 2014

# It Is Time To Stop Talking About Moving Data In Healthcare

We are forming a 20-member consortium that will build the health data market.

## LIFE INSURANCE

Mark Mullin  
AEGON USA, Inc.

Robert Benmosche  
American International  
Group

Andrew G. Arnott  
John Hancock Mutual Life  
Insurance Co.

Dennis R. Glass  
Lincoln National Corp.

Roger W. Crandall  
Massachusetts Mutual Life  
Insurance Co.

Steven A. Kandarian  
Metropolitan Life Insurance  
Co.

Theodore A. Mathas  
New York Life Insurance Co.

John E. Schlifske  
Northwestern Mutual Life  
Insurance

Larry Zimpleman  
Principal Financial Group,  
Inc.

John Strangfeld  
Prudential Insurance  
Company of America

Gentlemen:

On March 7, vitaTrackr entered negotiations with 66 companies across 9 health sectors to form its Founding Consortium. (Invitation attached)

vitaTrackr is a health data marketplace facilitating the movement of health data from point of creation to qualified destinations that value it. The vitaTrackr marketplace is an industry-wide utility benefiting all, but advantaging no individual sector or entity. We are independent and agnostic to all market participants. The consumer, (data owner) authorizes data transfers.

The vitaTrackr revolution: *“don’t compete on access to health data, compete on the value you add to it”*

On April 4, a company on this invitation approached vitaTrackr. From those discussions, it became clear the vitaTrackr model provides significant benefit to the Life Insurance sector.

## vitaTrackr and the Life Insurance Sector

- *Accelerate Application Process*
  - Virtually instant access to medical records
- *New Benefit Plans*
  - Adaptable to lifestyle
- *More data, more analysis, better assessments*

vitaTrackr is leading the movement with its 20 member Founding Consortium. Member selections are limited by industry sector; within each sector, members are selected based on industry leadership, innovation and commitment to customer. Each sector’s Founding Consortium representative(s) guides vitaTrackr’s development in that sector. Additionally, members are rewarded ownership in vitaTrackr. vitaTrackr has now added one seat to the Founding Consortium to represent the Life Insurance sector. Contact us, if you see the value of a connected health industry and want to be part of shaping it.

Brian J. Baum  
Founder/CEO vitaTrackr, Inc.

cc: Karen DeSalvo, MD, National Coordinator Health Information Technology



July 22, 2014

Chairman Fred Upton  
House Energy and Commerce Committee  
2125 Rayburn House Office Building  
Washington, DC 20515

Representative Diana DeGette  
House Energy and Commerce Committee  
2368 Rayburn House Office Building  
Washington, DC 20515

***SUBMITTED ELECTRONICALLY***

Chairman Upton and Congresswoman DeGette:

ACT respectfully submits the following to respond to the House Energy and Commerce Committee's 21<sup>st</sup> Century Cures Initiative request for comments.

ACT | The App Association is the leading organization representing over 5,000 small and mid-sized software companies in the mobile app ecosystem. Our members build the apps consumers use every day, at home, at work, and at play. As consumer use of mobile devices increases, privacy and security are increasingly important. ACT appreciates the opportunity to submit comments.

As the app industry has grown rapidly over the last few years, the emergence of the mobile health market has been equally impressive. The global mobile health market was estimated at \$1.2 billion in 2011 and is projected to increase to \$11.8 billion by 2018.<sup>1</sup> The health apps share of that market was \$150 million in 2012 and analysts expect this to grow 23 percent annually over the next five years.<sup>2</sup> Though a vital industry, the digital healthcare ecosystem is still growing and finding its legs.

**Health Apps are the Next Frontier**

More and more consumers are using health apps on their mobile devices to stay healthy. With a smartphone, users can connect to their physician from anywhere in the world and provide diagnostic data. Phones and tablets now serve as platforms that connect medical devices

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<sup>1</sup> Harry Greenspun and Sheryl Coughlin, "mHealth in a mWorld: How mobile technology is transforming health care," Deloitte Center for Health Solutions, 12 (2012) *available at* [http://www.deloitte.com/assets/Dcom-UnitedStates/Local%20Assets/Documents/us\\_chs\\_2012\\_mhealth\\_HowMobileTechnologyIsTransformingHealthCare\\_032213.pdf](http://www.deloitte.com/assets/Dcom-UnitedStates/Local%20Assets/Documents/us_chs_2012_mhealth_HowMobileTechnologyIsTransformingHealthCare_032213.pdf).

<sup>2</sup> *Id.* at 13.



allowing patients to monitor their blood pressure, glucose levels, and other vital statistics at home and transmit this data daily to a healthcare provider.

Mobile devices are also able to connect physicians with those in underserved communities, remote areas, or with limited mobility for whom office visits are difficult and occur infrequently. With connected wireless devices providing more and more diagnostic data, doctors can spot the early signs of adverse conditions and take preventive measures to improve health outcomes.

## Who Benefits from Mobile Health Apps?

Mobile health apps provide benefits to three distinct groups of users: healthcare consumers, healthcare professionals, and the healthcare industry. While these three groups use medical information differently, they all benefit from consumer generated and controlled health data.

### *Healthcare Consumers*

Healthcare consumers are the most conspicuous group of health app users. In 2012, over 247 million users had downloaded a health app to their mobile device.<sup>3</sup> These apps can monitor steps, weight loss, sleep, and even pregnancy. They provide a way for consumers to be directly involved in their own healthcare and provide valuable data to their healthcare providers.

For example, mobile health company Withings produces a number of wearable devices, such as the Withings Pulse and Wireless Blood Pressure Monitor. These devices connect to an app on a mobile device that allows consumers to take measurements and monitor their progress. This information is stored on a mobile device, providing users with detailed history they can share with healthcare professionals.

In places where doctors can be hard to reach, mobile apps provide a needed connection to patients all over the world. Mobile apps provide healthcare information to rural areas and can track and address health epidemics, including in developing countries. Close to 90 percent of the world's population have wireless coverage and 65 percent of cell phone subscribers reside in developing countries.<sup>4</sup>

### *Healthcare Professionals*

Where physicians previously consulted a mobile device to quickly look up a medical term, mobile apps are now providing physicians with personalized patient information that can be used to make diagnoses, monitor progress, and directly connect with patients. Mobile apps allow a care team to better engage with a patient and can keep doctors informed on patient status to help

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<sup>3</sup> *Id.*

<sup>4</sup> "Mobilizing a revolution: How cellphones are transforming public health," Harvard School of Public Health Magazine (Winter 2012), available at <http://www.hsph.harvard.edu/news/magazine/mobilizing-a-revolution/>.



foster recovery. Physicians can prescribe health apps and medical tracking devices, like blood pressure cuffs and heart rate monitors, which connect to mobile devices and apps. Over a third of U.S. physicians have prescribed an app to a patient.<sup>5</sup>

Mobile apps also facilitate better communication between patients and providers to produce better health outcomes. Utah-based Orca Health provides healthcare professionals with brilliant images and graphics of the human body on a mobile platform to help explain to patients the nature and location of their injury or illness and the process for fixing it.<sup>6</sup> The 3D images give patients a better understanding of their medical conditions and allow them to make more informed healthcare decisions.

Medical professionals also use apps to make their jobs easier. Doctors use mobile devices and apps to monitor their patients and review charts. Texas-based AirStrip provides software running on both the Microsoft Surface and iPad that allows doctors and other medical professionals with access to patient medical information like x-rays, CT scans, and vital statistics in near real time. Remote access to this information allows doctors to quickly assess patient conditions and determine a course of treatment, allowing them to react to any change in the patient condition and meet the needs of expanding patient populations.

Mobile apps help make telemedicine a reality for patients and reduces the problem of geography. Interknowlogy, a San Diego-based company, has created an app using Microsoft's Kinect that allows patients to perform their rehabilitation exercises at home and reports their progress to their healthcare team, even allowing a patient's healthcare team to monitor the patient's exercise remotely.<sup>7</sup> Ensuring that patients are properly performing physical therapy exercises helps speed recovery while reducing healthcare costs for patients, doctors, and the healthcare industry.

### *Healthcare Industry*

The healthcare industry is embracing mobile apps as a way to better serve their consumers. Mobile apps are used to reduce medical costs of patients, monitor progress of clinical trials, and reduce paperwork for billing, scheduling, and claims processing.

The healthcare industry turns to companies like Ideomed to provide medical apps to their consumers that assist in wellness objectives that also lower healthcare costs. Ideomed, a Michigan-based company, uses daily engagement through mobile apps to improve health outcomes of chronically ill patients. With an estimated 75 percent of every healthcare dollar spent

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<sup>5</sup> Jonah Comstock, "Survey: One third of docs recommend a health app to patients," *Mobi Health News* (29 May 2014) available at <http://mobihealthnews.com/33594/survey-one-third-of-docs-recommended-a-health-app-to-patients/>.

<sup>6</sup> Orca Health (last visited 9 June 2014) available at <https://orcahealth.com/features>.

<sup>7</sup> Interknowlogy Solutions Rehab With Kinect (last visited 9 June 2014) available at <http://www.interknowlogy.com/solutions/#rehab-with-kinect>.



on chronic conditions, Ideomed is addressing the economic need for a less expensive way to proactively manage chronic illnesses.

Ideomed CEO Keith Brophy testified before Congress that Ideomed's web and mobile-based engagement platform Abriiz has made a significant impact in addressing the chronic condition of asthma.<sup>8</sup> Abriiz is a health management platform that helps monitor patient medication compliance and track asthma symptoms. Data from a year-long pilot test indicates Abriiz was able to significantly lower emergency room visits. Ideomed understands the information collected by its apps is sensitive and takes steps to protect its users' data.

"An ounce of prevention is worth a pound of cure;" a sentiment that the healthcare industry is embracing with mobile apps. Health insurance companies are looking to mobile platforms like Abriiz, as keeping patients healthy helps to reduce costs, an outcome that benefits everyone.

## Ways Congress Can Promote the Digital Healthcare Ecosystem

### *Transparency in Law, Regulation, and Oversight of the Ecosystem*

Existing laws and regulations provide sufficient privacy enforcement options in the mobile health industry. The best approach for digital healthcare safety combines elements of public-private partnership to guide industry with best practices that conform to all applicable laws.

The 21<sup>st</sup> Century Cures Initiative provides a valuable voice in the mobile health debate. We encourage the Committee to continue to work with members of the digital healthcare ecosystem, with particular attention to small businesses. The leading innovations are happening right now in small companies and new entrants. Large or small, businesses of any size need transparent and up-to-date laws and regulations around the digital healthcare ecosystem.

### *Work to Promote Interoperability of Health Data*

Interoperability helps promote patient safety, improve quality of healthcare, and reduce costs. One of the biggest challenges developers face when building health apps is the lack of interoperability with health data and transmission.

The Office of the National Coordinator for Health Information Technology (ONC) has been tasked with information operability. The oversight role Congress plays will be critical to ensure that the administration meets these requirements.

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<sup>8</sup> "Testimony of Keith Brophy, Chief Executive Officer, Ideomed" House Committee on Small Business Subcommittee on Health and Technology (27 June 2013) *available at* [http://smallbusiness.house.gov/uploadedfiles/6-27-2013\\_brophy\\_testimony.pdf](http://smallbusiness.house.gov/uploadedfiles/6-27-2013_brophy_testimony.pdf).



Further, we ask Congress to work to ensure that federal and state privacy laws around health data are harmonized. Those in the digital healthcare ecosystem work hard to follow rules around privacy and security. Conflicting regulations lead to confusion and marketplace uncertainty which stifles investment and innovation.

### *Increase Speed of Technology Assessments by Regulatory Agencies*

As we learned through the FDASIA process, agencies and other regulators are not always keeping up to speed on the fast changing health IT marketplace. We think it is vital that agencies conduct technology assessments more frequently.

Multi-stakeholder forums can provide a space to both showcase and question how new groundbreaking technologies can be utilized in healthcare and force a review of regulations that are causing barriers simply by being out-of-date.

### **Conclusion**

We appreciate Chairman Upton and Representative DeGette's support and leadership in this field and ACT | The App Association looks forward to working with the Initiative to help promote and grow the digital healthcare ecosystem. Thank you for the opportunity to comment on this important issue.

**ACT | The App Association**

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**AdvaMed**

Advanced Medical Technology Association

**The Advanced Medical Technology Association's (AdvaMed) Comments on  
21<sup>st</sup> Century Cures: Digital Health Care White Paper  
Submitted to the House Energy and Commerce Committee  
July 22, 2014**

AdvaMed enthusiastically supports the efforts of Chairman Upton, Representative DeGette, and the Energy and Commerce Committee on the 21<sup>st</sup> Century Cures initiative. The medical technology industry is central to the development of medical devices and diagnostics that will provide the life-saving and life-enhancing treatments of the future.

AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our members range from the smallest to the largest medical technology innovators and companies. Nearly 70 percent of our members have less than \$30 million in sales annually.

We appreciate your interest in the topic of digital health care. Within the broader topic of digital health care, we have a specific interest in the regulation of health information technology. As you know, this area of technology is undergoing tremendous growth, and it is important to ensure that patient safety remains our highest priority, while still encouraging innovation.

AdvaMed believes that the following four broad principles are critical for effective regulation of health information technology (IT):

1. Regulation of either software or health IT (including software) should be platform agnostic.
2. If a product fits the current definition of a medical device, it should be regulated as a medical device.
3. Where appropriate, regulating agencies should collaborate.
4. Regulation should harmonize with well-established international standards.

**The FDASIA Health IT Report**

We are encouraged that the "FDASIA Health IT Report" (released April 3, 2014) takes a risk-based approach to the oversight of HIT and suggests that FDA, FCC, and ONC direct their focus and resources on those technologies that have the most potential to impact public health. We also appreciate the agencies' commitment to developing a flexible framework for overseeing HIT that recognizes the rapid evolution of these important products. Lastly, we agree with the report recommendation that FDA focus its attention on medical device health IT functionality.

Our full comments on the FDASIA report are attached.

## **Regulation of HIT and Mobile Apps**

With respect to regulation of health information technology, including mobile applications, we believe that FDA should focus its resources on those products that present the highest risk for patients. Additionally, we believe that regulation should be appropriate and should not be done for regulation's sake, but instead to protect the public health by ensuring safety and efficacy. Smart regulation can help innovation thrive. Overly burdensome and unpredictable regulation can hinder innovation.

In considering the question of how health IT and software should be regulated, it is important to note that software is increasingly being incorporated into traditional medical device products. Additionally, certain stand-alone software has been long-regulated by FDA as a medical device (i.e. radiation therapy software; PACS, or *picture archiving and communication system*).

The strength of the current definition of a medical device is that it is based on intended use of a product—not on the product's technological aspects. Thus, the definition has allowed for substantial and robust innovation in the medical device industry over the last nearly forty years. Just as the definition of a medical device was not tied to 1970s technology, it is not tied to technology of 2014 and can accommodate future innovation. As this innovation continues and software becomes more integral in health care and medical technology, this focus on intended use is critical. Shifting to a system that focuses instead on technological aspects of a product would be disruptive and would potentially place patients at risk.

Additionally, we are generally supportive of FDA's final guidance on the regulation of mobile medical applications, and we think this approach should remain as guidance, as opposed to being written into the statute. Guidance documents evolve, as industry and regulators develop better understanding of the technologies and their use in patient care. Given this, there could be a need to update FDA's mobile apps guidance in the future, and having it in statute would make this a cumbersome and time-consuming process and could hinder future innovation.

## **Risk Assessment**

Evaluating the risk of a product, software or otherwise, is part of the quality systems regulations (QS regulations) and all products that diagnose, cure, mitigate, treat or prevent disease should go through this same evaluation. There are several different, well-established methods used for risk assessment (i.e. Failure Mode Effects Analysis (FMEA), Failure Mode Effects and Criticality Analysis (FMECA), fault tree analysis, assurance cases and other common methods). These methods vary in their specifics, but all involve evaluating what could possibly go wrong with a product and how those negative outcomes can be mitigated. Companies then assess the risk of outcomes that cannot be mitigated and the odds of them happening. A typical risk analysis includes considering the product's end user (i.e. patient or physician). This basic approach is appropriate for both traditional medical devices and software products that meet the definition of a medical device.

## **A Suggested Approach**

Given our comments above and our desire to assist the Committee in their work on this issue, we offer the attached legislative language for your consideration. This language is platform agnostic, but recognizes that low-risk HIT could benefit from less regulation. Additionally, it recognizes that certain basic software products are not medical devices and avoids the unintended consequences referenced

above of de-regulating currently regulated medical devices. Lastly, it seeks to address the ambiguity involved in FDA's current "enforcement discretion" approach to certain HIT.

Below is a brief section by section summary:

**Section (1)** – General Sense of the Congress

**Section (2)** – Administrative and financial software is not a medical device and should not be regulated as such.

**Section (3)** – Wellness and Lifestyle products are not medical devices and should not be regulated as such.

The FDA guidance on regulation of mobile medical apps stated that FDA would take an enforcement discretion approach to mobile apps that are intended for individuals to log, record, track, evaluate, or make decisions or behavioral suggestions related to developing or maintaining general fitness, health or wellness. Some examples cited in the guidance are apps that:

- Provide dietary logs, calorie counters or make dietary suggestions;
- Provide meal planners and recipes;
- Track general daily activities or make exercise or posture suggestions;
- Track a normal baby's sleeping and feeding habits;
- Actively monitor and trend exercise activity;
- Provide and track scores from mind-challenging games or generic "brain age" tests;
- Provide daily motivational tips (e.g., via text or other types of messaging) to reduce stress and promote a positive mental outlook;
- Use social gaming to encourage healthy lifestyle habits;
- Calculate calories burned in a workout.

We do not believe that these are medical devices. There are products that are not apps that do the same things (i.e. calorie counter on the treadmill at the gym; magazines of brain-challenging games; books that provide calories in foods, and provide meal planners). FDA does not and should not regulate those products; thus it should not regulate apps with the same function.

**Section (4)** – Builds on the concept of risk by establishing that electronic patient records that functionally represent a medical chart, should not be subject to regulation as a medical device, provided that the software involved is validated prior to marketing with current standards for software validation. As electronic health records do carry some (albeit low) risk if the software involved alters or misrepresents patient data, the validation requirement is needed to ensure these risks are addressed. But again, these products are so low-risk that they do not warrant full regulation.

**Section (5)** – This section involves decision support software, which can involve more risk than those items covered in the previous sections. The language establishes that decision support software that is not a component, part or accessory of another device (or that serves the same or similar function as one) will not be subject to regulation as a medical device unless FDA demonstrates, after engaging in a public process, that the probable risks of not regulating that item outweighs the probable benefits to patients of not regulating the device type.

With this approach, all software products that fall into this category will be presumptively deregulated, unless FDA demonstrates that there is a need for regulation. Placing this burden on FDA will allow for those truly higher risk decision support software to be regulated, without requiring regulation for all decision support software.

Additionally, when FDA does decide to regulate one of these items (after going through the public process), it is important to note that regulation does not necessarily equate with having to go through the 510(k) or PMA process. It is likely that many of these products could fall into the class I category, because the risk posed to patients would be minimal. For class I exempt products, manufacturers would not have to submit a 510(k) but would be required to comply with QS regulations (quality system regulations) to ensure that the product consistently meets applicable requirements and specifications.

### **Conclusion**

Again, we appreciate the opportunity to provide comments and applaud your efforts on the 21<sup>st</sup> Century Cures Initiative. We look forward to discussing this with you.

520(o) REGULATION OF PATIENT RECORDS AND CERTAIN DECISION SUPPORT SOFTWARE. \_\_

(1) GENERAL. \_\_

(A) It is the sense of Congress that the public health will be better served by making patient related information more immediately available to medical professionals through software supported electronic media. Accordingly, consistent with the following paragraphs in this subsection, minimizing the cost and delays associated with regulation under the Act of software that is not a component, part, or accessory of another device should be the goal of the Secretary to ensure that medical professionals have expeditious access to patient records and certain decision support information in useable formats.

(B) To this end, the President and the Congress should work together to develop and enact legislation that reduces regulatory burdens, promotes patient safety, and fosters innovation for low risk software information products, based on determining a favorable balance of probable benefits to risks for such products.

(2) ADMINISTRATIVE AND FINANCIAL SOFTWARE. \_\_ Software that is intended solely for administrative or operational support or the processing and maintenance of financial records is not a device within the meaning of section 201(h).

(3) WELLNESS AND LIFE-STYLE PRODUCTS. \_\_ Products that are intended for use in activities unrelated to an existing deviation from a healthy condition and that are for the purpose of maintaining health and conditioning, are not devices within the meaning of section 201(h).

(4) PATIENT RECORDS. \_\_ Excluding image data, electronic patient records created, stored, transferred or reviewed by healthcare professionals or persons working under their supervision that functionally represent a medical chart, including patient history records, shall not be subject to regulation under this Act, provided that software designed to implement these functions is validated prior to marketing, consistent with the standards for software validation current at that time.

(5) DECISION SUPPORT SOFTWARE. \_\_

(A)(I) Software that is designed to analyze, alter or otherwise manipulate patient information for the purpose of making patient care recommendations to healthcare professionals to assist in patient care that is neither a component, part, or accessory, nor serves the same or similar function as a component, part, or accessory, of another device, shall not be subject to regulation under this Act, unless the Secretary within one hundred and eighty days of the effective date of this provision identifies in the Federal Register each such type of device that should be subject to such regulation. (II) Following this initial process, and after publishing a notice and proposed order, and receiving and analyzing comments on each such order, the Secretary may finalize the order to require a specified level of regulation for a type of software device described in (A)(I).

(B) For each type of device referenced in (A) that the Secretary determines requires regulation under the Act, the Secretary shall demonstrate that the probable risks of not regulating the type of device outweigh the probable benefits to patients of not regulating the device type. For each type of device that the Secretary identifies as requiring regulation under the Act, the Secretary shall specify the level of regulation necessary to provide a reasonable assurance of safety and effectiveness for the type of device.

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July 7, 2014

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
Rm. 1061  
Rockville, MD 20852

***Re: Docket FDA-2014-N-0339***

***“Food and Drug Administration Safety and Innovation Act (FDASIA) Health IT Report:  
Proposed Strategy and Recommendations for a Risk-Based Framework”***

Dear Sir or Madam:

I am writing on behalf of the members of the Advanced Medical Technology Association (AdvaMed) in response to the draft FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework.

AdvaMed is the world’s largest association representing manufacturers of medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our members range from the smallest to the largest medical technology innovators and companies. Nearly 70 percent of our members have less than \$30 million in sales annually. Patient safety is our industry's highest priority.

There is no purpose to making medical devices that place patients at unnecessary risk. This philosophy extends, of course, generally to Health IT and specifically to Medical Device software. Consequently, we are particularly interested in the draft FDASIA Health IT Report’s risk-based framework and regulatory control proposals. In this letter, we will describe our primary philosophical position and additional explanatory comments addressing some of the specific sections of the report.

### **The AdvaMed Position**

Fundamentally, AdvaMed believes that the following broad principles are critical for an effective effort to regulate Health IT.

## 1. Platform Agnostic.

Regulation of Health IT should be platform agnostic. By "platform agnostic" we mean that neither the platform used to run Health IT nor any IT hardware that is part of the Health IT should determine whether or how it is regulated nor, if it is regulated, which agency regulates it, e.g., software running on a phone or driving an eyepiece or other medical device display should be regulated the same when they share the same function. The regulatory controls imposed upon the Health IT product's developer should be based upon the risks associated with the device's intended use, not the technology employed.

## 2. Intended Use.

Health IT, that by virtue of its intended use as stated by the manufacturer fits the Federal Food, Drug & Cosmetics Act definition of a medical device<sup>1</sup>, should be subject to FDA regulation, as it is now. The current test for whether a product falls under the FDA medical devices regulation is whether it meets the Act's definition of a medical device. We believe that Health IT should be handled similarly to other FDA-regulated medical devices.

Medical devices that are categorized as Health Management HIT and that meet the definition of the regulation above should be considered by the FDA as so low risk that they should not enforce compliance with the regulatory controls including registration and listing, premarket review, postmarket reporting and the quality system regulation for manufacturers of these types of devices.

Additional FDA authority or law is not needed to establish a new regulatory schema, with the exception of creation of a means to place these Health Management HIT medical devices into a new Class "HMHIT" (Health Management HIT).

Within this proposed Class HMHIT as well as the entire Health Management Functionality category, it would be expected that a further separation of those products within this new category would be needed to better manage the diversity of products. Therefore there is an understandable need for a scaling level of controls based on the risk and user's dependence on the product.

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<sup>1</sup> A device is: "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
- intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
- intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes."

### 3. Exempt Low Risk Health IT Medical Devices.

We applaud FDA's decisions to exempt low risk Health IT medical devices from active regulation. Issuance of the Mobile Medical Application guidance in September 2013 brought clarity to many aspects of the regulatory schema, e.g., manufacturers of smartphones will not be regulated. The more recent posting of an MMA exemption example (June 11, 2014) and issuance of the draft MDDS guidance (June 20, 2014), in our opinion, correctly remove unnecessary regulatory burdens to Health IT medical devices that will receive data downloaded from actively regulated medical devices and/or display, store or transmit patient-specific medical device data. These decisions bode well for future Health IT risk evaluations and decisions. It will be important, however, to maintain certain expectations, as defined in the FDASIA report, to ensure that the products marketed in this space maintain the needed level of quality, safety, and effectiveness. We agree with the need for these products to be manufactured and designed with a clear set of quality principles and standards. We also agree that an appropriately defined certification process for certain products would also support this goal. Any such system should recognize compliance with FDA quality system regulations in lieu of an additional system, should an FDA-regulated company decide to address in this manner. An alternative to FDA's adverse event reporting process will also be vital to patient safety in the event of a product failure.

### 4. Guidance and Regulation in Partnership.

The FDA needs to be nimble in establishing and modifying regulatory controls to respond to the rapidly evolving Health IT industry products. In this ever changing environment, FDA needs to be able to share new risk evaluations and regulatory decisions with industry and the public in a timely manner; Communicating key regulatory decisions with industry and the public via issuance of guidance documents and posting notices on the Agency's website is a useful and productive first step in the process. We encourage FDA to continue doing so. However, to ensure a predictable and consistent set of regulatory requirements, it is critical that FDA follow through with changes to classification regulations where necessary, e.g., 21 CFR 880.9(c), 21 CFR 880.6310, 21 CFR 892.2010, and 21 CFR 892.2020. The updating of these regulations and establishing a Class "HMHIT" for Health IT medical devices that are not be subject to FDA regulation will reduce industry uncertainty and foster the Health IT innovation desired by all. This approach is both flexible and sustainable. Generally we believe FDA and ONC needs to take a proactive approach in avoiding duplication or redundancy of regulations.

### 5. Accessory to Actively Regulated Medical Device.

Historically, the FDA has generally regulated products that connect to medical devices by placing them in the same regulatory classification as the medical device. FDA has considered these connected products to be accessories to the medical device. This approach ignores the intended use of the connected product, can overestimate the risk associated with that intended use, and may impose unnecessary regulatory controls.

Recently, the FDA took an important step forward on June 20, 2014 with the issuance of “Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices - Draft Guidance for Industry and Food and Drug Administration Staff” which clarified the intention of FDA to consider these MDDS and certain Mobile Medical Application products to be under enforcement discretion.

This regulatory decision is based upon the Health IT product’s inherent risk, not upon the parent device’s risk. We agree with this decision. We hope that basing regulatory controls upon Health IT product’s risk will become the common practice.

6. Three Tier Approach.

The FDASIA Report proposes a three tiered approach, suggesting there are distinctions between administrative, health management, and medical device Health IT products, and the regulatory schema should reflect those distinctions. We agree. The regulatory schema for these three categories should be based upon the products’ risks. We also agree with FDASIA Report authors’ acknowledgement of Health IT products that include functionalities associated with more than one of the three categories. There are and will be Health IT products with functionality that fall within more than one of the categories. The Health IT regulatory schema must anticipate these products, and should provide a predictable and efficient means of commercializing these Health IT products. The Health IT should be a continuum of regulatory requirements to avoid redundancy, inconsistency, and unnecessary burden to the industry.

7. Health IT Safety Center.

Establishing a regulatory schema that encourages continuous learning and improvement is a pivotal component of success. Failure to establish this information sharing forum will shunt the growth of Health IT. The final configuration of the Health IT Safety Center must include subject matter experts from Medical Device and Software companies who will work in collaboration with the three agencies. Currently, however, we do not have enough information to endorse the proposed creation of a Health IT Safety Center.

8. Clinical Decision Support.

Clinical Decision Support software should be evaluated in the same manner as other Health IT devices, i.e., build a risk-based framework to decide which, if any, regulatory controls should be imposed upon each CDS function.

We encourage the development of a risk-based framework that examines the user’s level of dependence upon the software function in order to determine the Health IT device’s categorization. We recommend developing a regulatory schema that takes into consideration: transparency of inputs and clinical rationale, competency of the user, and time to reflect before making a decision, to determine if the user is dependent on the information being provided.

A clear definition of Clinical Decision Support is essential. We offer the following suggestion: CDS definition: “software providing users with clinical knowledge and patient-related information intelligently filtered or presented at appropriate times, to enhance patient care.”

#### 9. Health and Wellness.

The categorization of Health IT products within the scope of the FDASIA report must consider the dividing line between products solely intended for “health and wellness” applications and products with Health Management function.

Historically, it has been possible to draw a line between health and wellness products and medical devices. This line becomes blurred over time with some Health IT products. Our society encourages its citizens to improve personal health by optimizing diet, exercise, and other lifestyle factors. Health IT products will serve a vital role in educating and motivating people in health maintenance and disease prevention. We encourage the FDASIA work group to establish a predictable, risk-based regulatory framework which clarifies the current regulatory distinction between health and wellness products and medical devices. This will continue to foster the innovation of these important health-supporting products.

#### 10. Global Harmonization.

Historically, a leading inhibitor of medical device innovation has been the lack of global harmonization of regulatory requirements. This lack of global regulatory harmonization may force country-specific verification and validation activities and lifecycle management decisions, which is both costly and complex. This cost and complexity can easily stifle innovation. Building a domestic Health IT regulatory schema upon well-accepted, international consensus standards and technical reports, e.g., ISO 14971, IEC 62304, and IEC/TR 80002-1, should lead to a regulatory environment that protects the public from unnecessary risks while still enabling innovation.

#### 11. Third-Party Organizations.

We believe third-parties can serve an important role. The key areas are the development of consensus standards, design guidelines, and independent certification programs; each supported by inclusive and transparent processes. Any such certification program should also recognize compliance with FDA quality system regulations in lieu of an additional system should an FDA-regulated company decide to address in this manner. We believe third-party organizations can serve the role efficiently and robustly; the regulatory schema should leverage these third party resources. We suggest that it is important to adhere and be certified to appropriate process standards that reflect the necessary quality management principles supporting the categorization of Health IT in the risk framework (Administrative to Health Management to Medical Device) based on scientific evidence.

We appreciate the opportunity to offer these comments, and look forward to working with FDA, ONC, and FCC to refine the risk-based regulatory framework. If you have any questions or would otherwise like to contact me, I can be reached at [REDACTED] or [REDACTED]

Respectfully submitted,

[REDACTED]

Jeffrey Secunda  
Vice President, Technology and Regulatory Affairs  
Attachment

AdvaMed Comment Form

Date: 7 JUL 2014

Document Title: **FDASIA Health IT Report; Docket FDA-2014-N-0339**

Submitters Name: Jeffrey Secunda

Company: AdvaMed

# A	Page/ Section/ Paragraph/ Line	Type: Technical Editorial	Proposed Change	Comment: Rationale/Justification for Change
1	Pages 4 and 17	Technical	With regard to the statements at the top-right of page 4, "...the creation of a Health IT Safety Center...be created by the ONC, in collaboration with FDA, FCC, and the Agency for Healthcare Research and Quality (AHRQ), with involvement of other Federal agencies, and other health IT stakeholders..." It is recommended the ONC consult with the Software Engineering Institute (SEI) at Carnegie Mellon University in Pittsburgh, PA during the development of this center.	The SEI can contribute valuable support to help answer the question(s) posed on page 17 of the report, such as, "How do we assure stakeholder accountability for adoption of quality management principles?" and "Is there a role for a non-governmental, independent program to assess stakeholder adherence to quality management principles?" The SEI and has been in place for over four decades. It would serve health IT stakeholders well to enable the ability to leverage this foundational knowledge and expertise the SEI has achieved. Their current repository of lessons learned, information, tools, processes, and data may be valuable for the ONC to use as a basis for standards, best practices, tools, and continuous improvement for health IT. An overview of the goals and capabilities of the SEI is found here: <a href="http://www.sei.cmu.edu/about/">http://www.sei.cmu.edu/about/</a>
# B	Page/ Section/ Paragraph/ Line	Type: Technical Editorial	Proposed Change	Comment: Rationale/Justification for Change
2	Document as a Whole	Technical	N/A, general comment applicable to the regulation of products that fall within each category outlined in the report.	To promote innovation and preclude regulatory inefficiency, the FDA should be the only agency that approves "medical device health IT functionality". Government agencies should publish clear statements of jurisdiction applicable to "administrative health IT functionality" and "health management health IT functionality" as well as products with "administrative health IT functionality" and/or "health management health IT functionality" in combination with "medical device health IT functionality".

3	3/paragraph 1	Technical	N/A, general comment related to the statement "Overall, we do not believe that regulation should be or needs to be the first approach used to reach this outcome."	AdvaMed agrees with this statement. We believe the report's recommendations related to health IT software quality, consensus standards, and interagency coordination – combined with guidance published by the FDA – are more supportive of innovation than the introduction of new legislation that redefines certain sections of the Federal Food, Drug, and Cosmetic Act.
4	Page 4/ paragraph 1	Technical	<p>Change:</p> <p>"As such, if a product with health management health IT functionality meets the statutory definition of a medical device,<sup>2</sup> FDA does not intend to focus its oversight on it."</p> <p>to:</p> <p>"As such, if a product with health management health IT functionality meets the statutory definition of a medical device,<sup>2</sup> the FDA will consult with ONC and other stakeholders (public and private) to determine the appropriate risk-based regulatory approach."</p> <p>Note: Similar statements in the document (i.e., paragraph 4.2, Figure 2, paragraph 5.4, paragraph 6) should be reexamined.</p>	<p>AdvaMed is concerned that this statement may cause confusion among manufacturers since the FDA's Guidance on Mobile Medical Applications defines a "Mobile Medical App" as follows (including the footnote):</p> <p><i>C. Mobile Medical Application (Mobile Medical App)</i> For purposes of this guidance, a "mobile medical app" is a mobile app that meets the definition of device in section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&amp;C Act)<sup>4</sup>; and either is intended:</p> <ul style="list-style-type: none"> <li>• to be used as an accessory to a regulated medical device; or</li> <li>• To transform a mobile platform into a regulated medical device.</li> </ul> <p><sup>4</sup> Products that are built with or consist of computer and/or software components or applications are subject to regulation as devices when they meet the definition of a device in section 201(h) of the FD&amp;C Act.</p> <p><u>The FDA should remain the sole agency responsible for the regulation of products that meet the definition of a "device" in section 201(h).</u> For products with "health management health IT functionality" that meet the statutory definition of a device, the FDA must officially define alternative regulatory schemas</p>
5	Page 12/ paragraph 4.3	Technical	<p>Change:</p> <p>2) Medical device accessories; 3) Medical device clinical decision support software;</p> <p>to:</p> <p>2) Medical device accessories<sup>X</sup>; 3) Medical device clinical decision support software<sup>Y</sup>;</p> <p>Where "X" and "Y" are appropriately numbered footnotes that reference proposed guidance development priorities for CDRH Fiscal Year 2014 (FY2014). (<a href="http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/mdufaiii/ucm321367.htm">http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/mdufaiii/ucm321367.htm</a>)</p>	<p>Since both of these items are identified in the "B-list" for FY2014 guidance, adding two footnotes is an informative and appropriate addition to the document.</p> <p>AdvaMed urges the FDA to publish draft guidance for "Medical device accessories" and "Medical device clinical decision support software" during FY2014. Further, this report and recent legislative activity support a higher priority for these two guidance documents.</p>

6	Page 25/ paragraph 5.4	Technical	The comment addresses the question "How can the private sector help facilitate the development of a non-governmental process for listing selected health IT products? What types of products and information should be included? Should the results of conformity assessments, such as conformance with certain clinical or privacy and security standards, be included?"	AdvaMed strongly supports the use of consensus standards as a means of satisfying regulatory compliance requirements. For conformity assessments that reference certain privacy or security standards, care must be taken to ensure that sensitive information is not inappropriately disclosed. (See AdvaMed comment 32, Docket FDA-2013-D-0616)
7	Page 27/ paragraph 6	Technical	The comment addresses the question "What types of CDS functionality should be subject to the health management health IT framework? Which types should be the focus of FDA oversight?"	CDS software that meets the definition of a "device" in section 201(h) of the FD&C Act should be subject to FDA oversight, not necessarily FDA regulation. As indicated in a previous comment, the FDA should remain the sole agency responsible for the regulation of products that meet the definition of a "device" in section 201(h). For products with "health management health IT functionality" that meet the statutory definition of a device, the FDA must define alternative regulatory approaches through new guidance documents or other instruments (e.g., MOUs).
8	Page 27/ paragraph 6	Technical	The comment addresses the question: "Are there additional safeguards for CDS, such as greater transparency with respect to CDS rules and information sources that are needed to appropriately balance patient safety and the promotion of innovation?"	Transparency and intended use are both critical considerations for CDS. CDS software should be supported by applicable clinical guidelines and/or peer-reviewed journal articles in order to ensure patient safety. A product's "intended use" should include the consideration of whether it could engender physician dependence in emergency or critical-care scenarios.
# C	Page/ Section/ Paragraph/ Line	Type: Technical Editorial	Proposed Change	Comment: Rationale/Justification for Change
9	Page 4/ Section 1/ First paragraph/ line 3-8 of page	Technical	"...is a product with health management IT functionality meets the statutory definition of a medical device, FDA does not intend to focus its oversight on it. Rather, FDA would focus its attention and oversight on medical device health IT functionality, such as computer aided detection software..."	This approach returns to the mindset presented in the mobile apps guidance that does not remove products from oversight, but rather focus, from FDA's enforcement responsibility. Modifying the current focus of the regulatory agency rather than making a clear determination on product marketing requirements produces confusion and reduces predictability for the industry. The FDA must provide clear delineations between products that fall under the scope of the FD&C Act and those that do not. For those that do not but still fall under the definition of a medical device, FDA must publish clear expectations that those products must meet prior to marketing, even if this is not the current 510(k) or Class I exempt pathway.

10	Page 11/ Section 4/ Second Paragraph	Technical	"It is also important to note that the systems that healthcare organizations and consumers are purchasing, implementing, and using, often contain functionalities that bridge all three of these categories.....Similarly, some functionalities, such as privacy and security, cannot be placed in a single category."	First, there is a need to provide better clarity on how to regulate products that perform functions that fall in multiple categories. This situation exists for standard medical devices that also perform a non-medical device function but this issue will likely increase with advancing technology where there are more opportunities for connected solutions. This is also particularly important since it is being proposed that there may be a division of responsibility between FDA and ONC. Secondly, the later sentence suggests the need for a wider scope approach to privacy and security since the majority products will be affected by these challenges.
11	Page 12/ Footnote 35	Technical	Footnote 35: "Clinical Decision Support (CDS) provides health care providers and patients with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care. Because risks are generally low compared to the potential benefits, FDA does not intend to focus its oversight on most clinical decision support. FDA instead intends to focus its oversight on a limited set of software functionalities that provide clinical decisions support and pose higher risks to patients, such as computer aided detection/diagnostic."	Need clarity on terms: <ul style="list-style-type: none"> <li>• Intelligently filtered</li> <li>• Enhance health and health care</li> </ul> Again, and throughout this report, FDA claims that it "does not intend to focus" on certain products. This needs to be defined and a clear line drawn on what FDA will and will not regulate over the longer term. It is also essential that the expectations are clearly and formally defined for those products that the FDA does not plan to regulate. It is currently unclear which products will be transferred to the Health Management classification and which will remain in the Medical Device classification. While examples are helpful in clarifying the intent of the classification structure, it is equally, if not more, important to have a clear description and defining criteria that will place a product in one of the classifications. Clinical decision software, in particular, is a very diverse group of products that can represent a wide variety of risk to patients if poorly designed and produced.
12	Document as a Whole	Technical	Clarification on: Enforcement Authority	There is a need for clarification on the source for enforcement authority of ONC over the Health Management products in the Health Management Functionality category. It was explained at the FDASIA workshop (May 13-15, 2014) that ONC may receive enforcement authority over this group of products and that those products would no longer fall under the scope of the FD&C Act. It is currently unclear from where the current authority for ONC to regulate or oversee these products would originate.

13	Page 15/ Section 5.1	Technical	Clarification on: Quality Management Principles	<p>One of the recommended infrastructure components for the Health Management class of products is the promotion and use of Quality Management Principles. The use of such principles is essential to the development of reliable, effective products. The use of these types of principles should be required for at least some of the products that fall within the Health Management class of products. Not only is it important for the establishment of trust within that specific product but it is also essential for maintaining confidence in all of the products overseen via this alternate regulatory schema. If the use of basic quality principles is not required but instead established as an optional approach, this has the potential to decrease the likelihood of adoption by clinicians of a larger breadth of products because of a basic lack of quality and reliability.</p>
14	Page 8/ Column 1/ Paragraph 1	Technical	<p>Clarification on: Adverse event system          "The Workgroup recommended that... and 2) a surveillance mechanism is needed to track adverse events and near misses for certain health IT functionality that is not regulated."</p>	<p>The proposed adverse event system was described at the FDASIA workshop as "non-punitive" in nature and likely separate from the current FDA adverse event process. Clarity is requested in how this alternate system would allow traceability to similar or related issues within the FDA MAUDE database. Often health IT products are connected either directly or in common workflow practice with other medical devices and therefore the ability to perform root cause analysis is dependent on the connection of this relationship. It is also important for the calculation of valuable metrics so that events in health IT can be gathered alongside related medical device events. Lastly, it is clear that the impetus for establishing a non-punitive adverse event reporting system encourages high levels of reporting frequency but it is also important that this activity is balanced with structured surveillance for patterns that suggest a fundamental flaw or developing issue that may need enforcement to be addressed. It is currently unclear how that enforcement would be established.</p>
15	Document as a Whole	Technical	Clarification on: Standards	<p>What standards organizations will be leveraged for the standards development for interoperability and creation of standardized data exchange to promote safe use of data that is exchanged (p. 9)? Will there be a focus on currently-available standards (HL7, IHE) or are they proposing new development of new standards with alternate standards organizations (NIST)? The scope of impact to the medical device industry will differ greatly depending on the answer to this question. AdvaMed supports the leveraging of existing standards whenever possible to ensure clear, efficient implementation.</p>

16	Document as a Whole	Technical	Clarification on: Overall Implementation	<p>Is the proposed approach for administrative and health management functionality similar to the EU CE marking conformity assessment? It would seem that this may present a good model for fostering innovation while still maintaining accountability. Similar to how the notified bodies (NB) are responsible for certifying manufacturer's quality system, but the competent authorities still maintain accountability on the notified bodies, and by extension, on the manufacturers. One possibility may be to have the administrative health IT self-declared and the health management health IT may involve a notified body certification (a parallel to devices that Class I (self-declared) and Class IIa or Class IIb (NB involvement) in the European Union.</p>
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# D	Page/Section/Paragraph/Line	Type: Technical Editorial	Proposed Change	Comment: Rationale/Justification for Change
17	Document as a Whole	Technical	<p>General comments to promoting using existing standards. There are a wealth of established Health IT standards and FDA guidance that encompass the breadth of health IT functionality, including medical device:</p> <p>ISO 13485: 2003 Medical devices – Quality management systems – Requirements for regulatory purposes  ISO 14971: 2007 Medical devices- Application of risk management to medical devices  IEC 62304: 2006 Medical device software – Software lifecycle processes  ISO 62366: 2007 Applicability of Usability Engineering to Medical Devices</p> <p>IEC 80001-1:2010 Application of risk management for IT Networks incorporating medical devices, Part 1 – Roles, responsibilities and activities (addresses both devices and networks )  ISO 27799 Health Informatics – Information security management in health using ISO/IEC 27002  ISO/TR 27809:2007 Health informatics -- Measures for ensuring patient safety of health software  ISO/TS 25238:2007 Health informatics - Classification of safety risks from health software  ISO 82304-1, Healthcare Software Systems  ISO/IEC TR 80002-02, Medical device software - Part 2: Validation of software for regulated processes  ISO/TR 17791:2013, Health Informatics – Guidance on standards for enabling safety in health software</p> <p>FDA Guidance, Sept 25, 2013, Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff.  FDA Draft Guidance, June 20, 2014, Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices</p>	<p>Quality Management Systems need to allow manufacturers to apply a single process that satisfies the requirements of all agencies. Existing safety and quality-related processes, systems, and standards should be leveraged for patient safety in health IT.</p> <p>Health IT should leverage recognized standards for assuring patient safety.</p> <p>There are also a significant number of other ISO health IT related standards currently undergoing development and revision by ISO TC 215.</p> <p><b>Standards currently undergoing development and revision by ISO TC 215 :</b> <a href="http://www.nsa.gov/NSA/Files/5a/5aa28cf0-5d29-4ffe-94cf-83629d4e8a84.pdf">http://www.nsa.gov/NSA/Files/5a/5aa28cf0-5d29-4ffe-94cf-83629d4e8a84.pdf</a></p>  <p>Adobe Acrobat Document</p>
18	Page 4/ 1st column/ line 12	Technical	<p>General comment that patient safety should be expanded to include elements of patient safety such as hazards, security, health information (HIPAA).</p>	<p>The section is ambiguous on elements of safety and to what safety applies.</p>

19	Page 10/ 2nd column/ item 2	Technical	<p>General comment to item 2: "2) Individual health IT components may meet their stated performance requirements, yet the system as a whole may yield unsafe outcomes."</p> <p>Existing standards exist for health IT from a system perspective. Application of these standards would, in part, meet the concern for system safety concerns.</p>	<p>Expect compliance to applicable standards that support system safety, such as:</p> <p>IEC 80001-1:2010 Application of risk management for IT Networks incorporating medical devices, Part 1 – Roles, responsibilities and activities (addresses both devices and networks )</p> <p>ISO/IEC TR 80002-02, Medical device software – Part 2: Validation of software for regulated processes (draft) may be applicable as well</p>
20	Page 15./Sections 5.1 and 5.2	Technical	<p>Quality management systems already exist that allow flexibility to determine the necessity of individual quality elements and to tailor the development and implementation of quality management processes appropriate for their products and services.</p>	<p>Medical Device manufacturers operate under quality management systems and principles, and can provide the expertise in developing guidance in these areas.</p>
21	Page 15/ Section 5.1/ second paragraph/ third sentence, and last paragraph	Technical	<p>General comment that "configuration management" along with "customization" to read "customization and configuration management".</p>	<p>Configuration management is a critical element to maintaining customization and configuration changes/change control of Health IT systems</p>
22	Page 17/ Summary and Conclusion: input to 1st bullet question	Technical	<p>General comment that configuration management, change control, and defect tracking are essential quality management principles that apply to the health IT product lifecycle.</p>	<p>These are critical quality management principles to developing and maintaining Health IT systems.</p>

END OF COMMENTS



July 21, 2014

The Honorable Fred Upton, Chairman  
The Honorable Henry Waxman, Ranking Member  
Committee on Energy and Commerce  
2125 Rayburn House Office Building  
Washington, DC 20515

Dear Chairman Upton and Ranking Member Waxman,

On behalf of Altegra Health, I am pleased to offer this response to the request for public comment on the 21st Century Cures initiative focusing on digital health care. Altegra Health's technology-based products are transforming the delivery of essential healthcare services through more personalized outreach to health plan members.

#### **About Altegra Health**

Altegra Health operates in all 50 states from 8 regional offices, headquartered in Miami Lakes, Florida, to provide a complete range of services to health plans, its members, and providers, including:

- Program Assistance: Identification and assisted enrollment into government-funded healthcare programs, community assistance programs, and privately-funded programs
- Quality Improvement: Analytics for the identification of gaps in care, including underserved beneficiaries, quality measurement and reporting; beneficiary healthcare communications; and beneficiary outreach to facilitate in-home care and/or care from a primary care provider
- Risk Adjustment: Risk analytics, encounter reporting, and chart audit/coding solutions
- Advisory Services: Consulting services that improve performance for plans and providers

Altegra Health works with some of the largest health plans and providers in the nation, including:

- Payers: More than 150 Medicare Advantage, Managed Medicaid, and Commercial Market plans
- Providers: Hospital systems, provider groups & integrated delivery networks
- Other markets: Accountable Care Organizations (ACOs), health insurance marketplace, ICD-10 transition

The mission of Altegra Health is to help healthcare organizations and their members receive the financial resources and other benefits to which they are entitled, enabling quality care at the right time, leading to improved health at a lower cost, and overall, a better quality of life. Altegra Health utilizes data to assist health plans in delivering integrated health-related interventions that are specifically tailored to their members. In carrying out this mission, Altegra Health is committed to maintaining the strictest regulatory compliance and data security for health plans and the members that they serve.



## **SMART Connect™**

Altegra Health's SMART Connect product helps improve health outcomes for health plan members by connecting them with care management support solutions. SMART Connect provides on-going, customizable and personalized eligibility, enrollment and healthcare education information for health plan members. Specific programs include, but are not limited, to:

- Managing chronic conditions
- General and specialized health risk assessments
- Hospital discharge program
- Emergency room (ER) avoidance program
- Glaucoma testing
- Controlling blood pressure

SMART Connect utilizes multi-channel outreach to members, including automatic interactive voice response (IVR) messages, text messages, Smartphone apps, and live outreach calls. Health plan members can choose to interact based upon their communication platform preference in the language of their choosing.

Altegra Health brings the strength of synergy between its analytics capability and automated communications services. Altegra monitors member responses through its web-based SMART Connect dashboard to each of the programs offered through SMART Connect and reports the impact to health plans and their care managers.

SMART Connect's dashboard allows care managers to track member interaction so that they can help members access needed services in the most efficient manner. Care managers can utilize the dashboard to work with health plan members to access the most appropriate follow-up care. Care managers also are alerted in real time to health plan members who need immediate support. Results show that these alerts allow care managers to intervene and avoid more serious and costly health issues.

This member-level interaction has resulted in improved access to care for health plan members. SMART Connect has been successful in receiving responses from approximately 80 percent of the members to whom it reaches out. The average impact of automated communications is between 3 – 12 percentage points of improvement in compliance levels. For instance, if mammogram rates are currently 65 percent for the health plan, the post-call rate can be expected to be between 68 and 77 percent. Additionally, members are overwhelmingly supportive of the information and interventions that SMART Connect provides.

## **SMART Appointment Scheduling™**

Similar to SMART Connect, SMART Appointment Scheduling increases the quality of care delivered to health plan members by utilizing multi-channel outreach to help them schedule needed appointments with their healthcare provider.



Altegra Health integrates data and analytics to formulate a complete and holistic view of a health plan member's needs. Valuable information outlining clinical history, critical elements needing provider attention, services to be ordered and diagnoses that might be missing are designed to fit in a one-page document called the SMART Confirmation™. This document is made available to providers to help facilitate an effective and productive visit.

Additionally, Altegra Health sends a SMART Care Card™ to each health plan member for whom it schedules an appointment. The SMART Care Card is a customized half-page card that lists only the health screenings the member still needs to address in a given year and also provides space on the back to list their medications and any questions they would like to review with their provider. The member can take it to their provider's office to ensure that the screenings they need are addressed during their appointment.

Interventions through SMART Appointment Scheduling have resulted in improved appointment compliance by health plan members and improved health outcomes.

### **SMART Connect and Maternal Health**

The maternal health management program is a comprehensive communications program designed to deliver "micro-education" relevant to each week of pregnancy and into the weeks after delivery: pre-natal, post-partum, NICU discharge (if applicable) and well-baby. By delivering on-going communications, the education is always appropriate to the health plan member's condition. Examples of information include, but are not limited to, those focusing on:

- Symptoms: breast sensitivity, morning sickness, mood swings, depression
- Nutrition: eating fish, safety
- Trimesters explained
- Healthy habits during pregnancy
- Importance of pre-natal care

Recently, an Altegra Health client, a Medicaid health plan, utilized this program. The program helped the plan reduce expenses while improving the quality of care for their pregnant members. Over the first 12 months of the program, an average of 688 members was engaged in the program. Additionally, the plan's "Timeliness of Prenatal Care" metric increased by 13 percent. This increase was due to the frequency and consistency of the program that encouraged the pregnant member to take the necessary steps to have a healthy baby.

Care managers were able to increase their caseload by almost 3 times due to the technology's ability to reduce the number of unnecessary, repetitive outbound calls. Altegra Health delivered this efficiency improvement by handling routine interactions with members (e.g., providing relevant information) and by facilitating live conversations between care managers and members only when members needed help.



Altegra Health also delivered double-digit improvement in key maternal health cost drivers, increased the gestational age at birth, and reduced the number of low-birth weight babies. As expected, this resulted in fewer babies entering the NICU.

### **COMMUNITY Link™**

Altegra Health's COMMUNITY Link product guides health plan members through an extensive database of more than 8,000 public and privately-sponsored community programs to which they may qualify.

Altegra Health proactively reaches out to health plan members using multi-channel communications to advise them about the COMMUNITY Link service and its benefits. In addition to its proprietary database which maintains information about the programs that a member may qualify for in his/her geographic area, Altegra Health utilizes a proprietary eligibility evaluation tool to determine the programs to which a member may qualify in a single interview. Further, Altegra Health provides advocacy and enrollment assistance to help members access these programs.

COMMUNITY Link program categories include, but are not limited to:

- Energy & utility assistance
- Home care & repair
- Nutritional assistance
- Rx discounts
- Telephone assistance
- Transportation assistance

In 2012 alone, Altegra Health helped health plan members secure approximately \$160 million in financial benefits through COMMUNITY Link. In 2013, Altegra helped over 200,000 members access benefits through COMMUNITY Link. Altegra Health's experience through COMMUNITY Link has shown that these benefits can positively impact a member's overall health and well-being, as well as deliver financial assistance to those in need of these services.

### **Conclusion**

Altegra Health is proud that its electronic services have helped improve health outcomes for health plan members. Altegra Health's services provide members with important, personalized information that they can utilize to receive appropriate healthcare services in a timely manner and access benefits to which they may be entitled. If you have any questions, Altegra Health would be happy to provide any additional information about the company and its services.

Sincerely,

Kevin C. Barrett  
President & CEO



July 22, 2014

The Honorable Chairman Fred Upton  
Committee on Energy & Commerce  
U.S. House of Representatives  
2125 Rayburn House Office Building  
Washington, DC 20515

Dear Chairman Upton and Committee Members:

The American College of Physicians (ACP), the largest medical specialty organization and second-largest physician group in the United States, representing 141,000 internal medicine specialists (internists), related subspecialists, and medical students, thanks you for the opportunity to provide input into these very important issues. We appreciate the Committee's efforts to address the significant gaps that exist between practice and potential within the digital health care arena.

Overall, we support the direction that the Committee is taking to address these gaps in the digital health care system, and respectfully offer our comments on the areas of concern identified by the Committee in the "21st Century Cures – Digital Care" white paper.

The ACP believes that, notwithstanding the very significant benefits to some, viewing the potential of health information technology (health IT) enabled care as only leading to "new" cures is too narrow a view; and one that risks the defocusing of policy away from what we believe are more immediate benefits of health IT that are relevant to the majority of Americans, as well as paving the way for reducing overall healthcare costs. Americans are now living longer and are generally healthier because of healthier life styles, better screening and prevention, more consistent identification and treatment of key chronic conditions, and advances in heart disease and cancer treatments. We believe that there is real potential for the emerging digital healthcare system to markedly broaden those advances – leveraging electronic health records to help further the consistent application of existing knowledge, and utilizing the EHR as a learning system to more quickly diffuse new knowledge and changes in best practices.

For example, if the goals of the Million Hearts® program, which call for more consistent attention to known and proven cardiovascular risk reduction strategies, were broadly applied

across the United States, a million new heart attacks and strokes could be prevented by 2017 – reducing healthcare costs. And while this can occur without new expensive discoveries and treatments, Million Hearts® does require the technical support of robust software within electronic health records along with financial incentives to physicians such that cardiovascular risk reduction is made a routine part of primary care.

We stress to the Committee, when drafting legislation, to guard against imposing new data collection and reporting requirements on physicians, as the benefits of more data collection and reporting to patients are unproven, and the impact of the administrative burden and distraction to physicians is clear.

We urge you to keep the following general concerns in mind as you move forward.

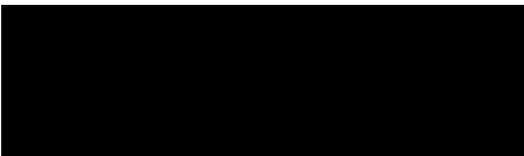
- The focus of what is done must keep both the patient and advancing the patient’s health and healthcare delivery in the center. As technology rarely presents a solution within itself, we believe that having a viewpoint that puts technology in the center of one’s thinking can add barriers between patients and doctors, and even to necessary care.
- That said, to advance health and healthcare, we cannot continue to add requirements for data collection and reporting that fall on physicians. Before EHRs, physicians used to complain that they “spent more time on paper work than on patient care.” And now with EHRs, the issue is expressed as “spending more time on EHR data collection and documentation than on taking care of patients.” We believe this widely held sentiment has led to a new barrier to physician optimization of health IT in clinical practice – and without reducing this barrier – the chances that new digitally based cures, such as those addressing underserved populations, will be appropriately used is low.
- Historically, in other fields that have experienced technology diffusion, over time IT and new digital workflows have made people more efficient. This has not been the case in medical practice. While EHRs and Meaningful Use have established a framework for making healthcare better and safer, instead of healthcare operations becoming more efficient, they have become less efficient. And while some have blamed the technology for this failing, we believe that the primary cause is the lack of a policy framework and guiding principle that supports optimization of physician time and the patient-physician experience. For example, where most information necessary for prior authorizations is contained within an EHR, payers still require uniquely formatted paper forms.
- EHRs and other physician-facing health IT cannot fix inefficiencies in healthcare operations without cooperation from both public and private payers. Meaningful Use requirements only address physician use of health IT. This imbalance in addressing the healthcare ecosystem has led to this paradox – what should make physicians more efficient (and thus lead to more time spent in patient care) has instead led to more administrative work and less face time with patients. Health IT would be able to achieve far more in terms of driving recommended care, if this imbalance was addressed and fixed.

- We encourage learning from past and current technology initiatives to inform new initiatives. The 21st Century Cures initiative is not the 1st attempt this century to use health IT to improve care. Has ePrescribing reduced medication errors and deaths from prescription medications? Have mandated clinical visit summaries been found to be valuable to patients? More study of the effects of specific health IT interventions is necessary
- Physicians want and need the ability to use data to learn and to perform better. It is self-evident to thoughtful physicians that data exchange per se does not improve care, and that too much data exchanged too broadly may make it harder to provide good care, and can lead to confusion due to “data overload” and potential misuse and/or misinterpretation of the data.
- The ACP was an early supporter of the objectives of the EHR Incentive program. However, generally, financial incentives are not as helpful as policy makers imagine. Incentives inevitably become penalties. This can lead to gaming behaviors intended to avoid the penalties, thus the behaviors will not result in the desired positive changes.
- We are concerned that, while the government is focusing on the goal of an information-rich healthcare environment, the formats that are being pushed are too often “data rich but information and knowledge/insight poor.” The focus should not be on the volume of data exchanged if these data do not add sufficient value or if they are difficult to find and separate from a large collection of less valuable data, or if the external data are delivered in formats that cannot be easily compared to local data and accurately reconciled. Specifically, a 2103 HHS RFI states, “HHS envisions an information rich, person-centered, high performance health care system where every physician has access to longitudinal data on patients they treat to make evidence-based decisions, coordinate care and improve health outcomes.” This statement contains the underlying assumption that there is a correlation between physicians having a larger quantity of clinical information about each patient, and patients having improved health. In fact, it is possible that such data overload could result in adverse consequences for patient care. More importantly, value-based goals for HIE should focus on the delivery of services, such as those mentioned, that facilitate decision-making, facilitate care coordination, and effectively measure and track health outcomes.
- The current MU-mandated exchange of patient summaries presents a clear warning about the risks of pursuing a policy of expansive and inadequately organized data exchange that too often “buries the headline” such that the most important information is so difficult to find that it is missed. What was once more typically a carefully crafted page and a half of relevant information has, through the requirements of MU, expanded to 7 or more pages – too much of which is not helpful to the receiving physician, who now has to scan through this bloated document to try to determine what matters (diagnosis and thought processes) and what has changed (medications, test results, treatment plans). The government should refrain from incentives that encourage exchange without conciseness and high usability.

- We want to see the government use the levers available to facilitate the kinds of exchange that matter most to patients, and thus to physician efforts to maximize quality, safety and value, such as those listed in the next bullet. Policies must minimize the number of connections and protocols that practices will have to establish and manage. Currently, many EHR vendors are charging each practice thousands of dollars to establish each connection, and to exchange each document type. Vendors are also signaling that there will be ongoing maintenance charges for each connection for each practice. In addition, vendors are so overwhelmed with work that they are unable to respond to the needs of small practices in a timely manner. There is nothing to be gained from policies that encourage exchange if the exchange partners do not have cost-effective and readily available connections.
- There are many opportunities for valuable exchange that should be encouraged through policy. These include:
  - Directories of provider contact information – complete and up to date.
  - Reliable and accurate patient identification and matching.
  - Rapid notifications of patient care activities such as emergency department arrivals, and admission and discharge notifications to ambulatory physicians.
  - Cross-system management of patient consent.
  - Support for quality measures that track patients across care settings.
  - Data cleaning and standardization services.
  - Management of longitudinal care records.
  - Data analytics, alerts and public reporting services.

The Medical Informatics Committee of the American College of Physicians respectfully submits this letter in the hope that it will assist the House Committee on Energy and Commerce in developing plans to advance a legal and regulatory framework that fosters the development of a digital health care ecosystem, and allows it to serve as a catalyst for the discovery, development, and delivery of new treatments and cures for patients, as well as a usable and useful infrastructure for the more efficient and consistent delivery of existing best practices.

Sincerely,



Peter Basch, MD, FACP  
Chair, Medical Informatics Committee  
American College of Physicians



American Society of Clinical Oncology

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July 22, 2014

Chairman Upton  
Chair, Energy and Commerce Committee  
2125 Rayburn House Office Building  
Washington, DC 20515

Representative DeGette  
2368 Rayburn House Office Building  
Washington, DC 20515

Dear Chairman Upton and Representative DeGette,

On behalf of the American Society of Clinical Oncology (ASCO), I am pleased to provide input on the 21<sup>st</sup> Century Cures Digital Health Care white paper, "Leveraging Technology to Advance the Discovery, Development, and Delivery of Better Treatments and Cures." ASCO appreciates your examination of how advancements in technology create opportunities to more rapidly and efficiently develop and deliver innovative treatments.

ASCO is the world's leading professional society representing physicians who specialize in the treatment of patients with cancer. With nearly 35,000 members, our core mission is to ensure that cancer patients have meaningful access to high quality cancer care.

ASCO supports the use of health information technology (HIT) and recognizes digital health technologies as a transformative force that will drive innovation in cancer care. HIT adoption among the oncology community is high, but there continue to be many challenges with its usage. We must focus on the gaps that remain between the potential of HIT to transform care and its practical utility to enhance the capture, aggregation, analysis and sharing of healthcare information at the present time.

Our scientific understanding of cancer and changes in information technology are advancing so rapidly that we are not yet able to fully leverage them. We have a greater understanding of the underlying drivers of cancer development and more effective ways to target those drivers with highly specific therapies. At the same time, outside of the clinical trial setting, we are unable to learn from most cancer patients – from the molecular characteristics of their tumors to the outcomes of their treatments. Only a small percentage of cancer patients participate in clinical trials. For those who do not participate in research, their information is locked away in unconnected electronic and paper records.

Oncology professionals face an enormous challenge to stay abreast of the rapid pace of scientific discovery and the introduction of novel treatments and molecular tests as we enter the era of precision cancer medicine. Oncologists would benefit from real-time decision support incorporating up-to-date recommendations to help them provide the most effective treatments tailored to the unique biology of each patient's tumor.

*Making a world of difference in cancer care*

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## **Barriers to Maximizing the Value of Digital Health Care**

Any federal legislation should facilitate communication across the HIT continuum to improve the quality of patient care while protecting the security of data. Policymakers should focus on addressing the current barriers to maximizing the value of digital health care: interoperability, usability and cost.

### ***Interoperability***

It cannot be overstated that the current lack of interoperability is a major impediment to fully recognizing the potential of HIT. Federal legislation should promote the development of more subspecialty standards and require adoption to drive electronic data exchange. More incentives are needed to create the environment for this to occur. Interoperability must allow the sharing of data across the care continuum- among providers at small and large institutions, community practices, academic settings, imaging centers, laboratories, pharmacies, payers, researchers and patients. It is also critical that there is a sharing of not just raw data, but annotation and physicians' interpretation of data, within and between systems and groups. This information sharing is the key to truly utilizing HIT's potential to improve clinical outcomes and coordination of care and drive new knowledge while improving the efficiency of care delivery.

Working through Health Level Seven International (HL7®), the leading standards developing organization for healthcare data, interoperability standards allow electronic health record (EHR) vendors and provider organizations to share data electronically agnostic to vendor or application, while preserving the semantic meaning. They also align with regulations cited in the Health Information Technology for Economic and Clinical Health (HITECH) Act's Meaningful Use of EHRs, part of the 2009 American Recovery and Reinvestment Act (ARRA).

ASCO's Health Information Technology Workgroup (HIT WG) is leading the development of interoperability standards for oncology. In order to improve oncology information exchange, ASCO published in 2013 the *HL7 Implementation Guide for Clinical Document Architecture (CDA), Release 2®: Clinical Oncology Treatment Plan and Summary, Draft Standard for Trial Use (DSTU) Release 1 (eCOTPS)*. The standard is based on ASCO's Breast Cancer Adjuvant Treatment Plan and Summary (TPS) (<http://www.asco.org/quality-guidelines/breast-cancer-treatment-plan-and-summary-resources>), which was designed as a paper rather than computer-based template. It is now available for implementation and trial use through [www.HL7.org](http://www.HL7.org). As a result, a large provider organization is implementing it in California for data transmission throughout their network for improved care of breast cancer patients.

ASCO's HIT WG created a "roadmap" to basic oncology data interoperability; histology-specific content for the most prevalent cancers will be added in an iterative process to the eCOTPS over the next five years. The second project, to be complete late in 2014, is underway and will incorporate data represented in ASCO's Colon Cancer Adjuvant TPS. The roadmap also includes content for Patient Reported and Survivorship information. However this work will only cover a small subset of oncology data. Because each of the projects spans a period of months, emerging and future interoperability standards should address the need for rapid expansion and development at a pace which has potential to keep up with the proliferation and complexity of healthcare information.

To advance awareness, development, and use of oncology standards, ASCO's HIT WG hosted its second Interoperability Standards Summit in June 2014. Representatives from approximately twenty organizations with a stake in the treatment of cancer across the care continuum, including federal agencies, professional societies, and healthcare providers, convened for an interactive meeting to discuss standards and interoperability. One of the gaps identified in existing healthcare standards is the need for more flexible capabilities; one of which is the ability to incrementally add new findings to a previously documented data point, such as a biopsy, while also preserving the original information. This, which may seem a minor capability, increases the time required to implement some standards in a way that will accurately transmit data and create more of a true, life-long, electronic health record. ASCO looks forward to continuing to work with stakeholders to advance interoperability for oncology.

### ***Usability and Cost***

Many EHR systems have a number of problems related to usability and functionality. Currently, data entry is often inefficient, requiring the same data to be recorded multiple times. For example, patients on clinical trials often have two sets of medical records, those contained in electronic case report forms created by the trial sponsor and those with their various providers. Technology should enable single data entry for research and clinical data to avoid errors between EHR and electronic case report forms and streamline clinical care and research. More functional and intuitive user interfaces, including capability to pre-populate discrete data such as pathology results in a clinical note, will help avoid reduplication of data and enhance efficiency. This will also help integrate the research process into the clinical care setting.

In many of today's HIT systems, there is a lack of support for efficient, multi-disciplinary clinical workflows and little actual use of clinical decision support for alert and educational purposes. Because many of the systems in use today were designed before the current needs, physicians and nurses often do not have the ability to extract data, create reports, or do complex analyses. Sometimes systems are implemented without adequate testing, which is beyond the ability of smaller organizations and community practices. Physicians want HIT that enables real time clinical decision support, analytics, quality reporting, the ability to communicate with other providers, and the incorporation of data from multiple sources. While it is acknowledged by many that these and other functionalities would add value to clinical care and important information for clinicians, the voice of specialty practices is often not prioritized by large, multi-solution vendors. It becomes difficult for them to manage the needs of all of healthcare in our rapidly changing environment.

The high cost to acquire HIT remains a barrier to adoption for many oncology practices. Federal legislative efforts should incent physicians to leverage new technologies to share information and improve clinical care.

The time has come to move beyond the concept of one vendor system that attempts to meet all needs toward a more modular approach that rewards innovation, use of current user interfaces, and incorporation of new devices and data capture methods into the healthcare setting.

### **Protecting Patient Privacy while Facilitating Information Exchange**

When adopting and using HIT, oncologists are keenly aware that maintaining patient privacy is of the utmost importance, but these protections should also work efficiently to improve data sharing and outcomes. Current overlapping and conflicting federal and state laws around patient privacy create a chilling effect on sharing patient health information across healthcare sites. Further, the current state of technology often fails to facilitate compliance with varying privacy laws such that oncologists choose to forgo information sharing altogether.

Effectively overcoming these obstacles to information sharing may be accomplished by establishing the necessary policy and technology infrastructure. Key components of such infrastructure include: (1) harmonizing, to the extent possible, varying federal and state privacy laws and regulations, (2) promoting innovation of technological solutions that can facilitate compliance with varying laws; and (3) creating incentives for physicians to engage patients to reduce misperceptions regarding the risks of information sharing.

The development of more robust technological capabilities to compensate for variations in privacy laws can help. Incentives, demonstration projects, and competitions could spur innovation in this area. As new technologies are developed and data are shared more widely, physicians must be assured that their care decisions are supported by the best available medical information and reliable technology. This includes the knowledge that technologies are providing accurate medical information while protecting patient privacy.

Patient engagement continues to be a key component to ensure transparency and appropriate notification and education. Oncologists work tirelessly to educate their patients about the importance of their health data's role in treatment and research. However, misperceptions and fears continue to exist regarding sharing of health information. As such, providing additional incentives to physicians to communicate with their patients regarding the benefits of information sharing for purposes of improving individual and population health could be important to drive change. Further, cancer patients are active in their support for data collection, yet consistency in patient privacy standards would facilitate their engagement and ease the process.

### **Improving Cancer Care with Digital Technology: CancerLinQ**

Each of these barriers has come in to play as ASCO moves towards integrating quality improvement programs seamlessly with EHRs. ASCO's Quality Oncology Practice Initiative (QOPI), the leading quality measurement and quality assurance program for medical oncologists, is in the process of transitioning to an electronic version where patient records are transferred in real-time. Additional information about QOPI is available at: <http://qopi.asco.org>.

ASCO's vision for the future of HIT in cancer care extends beyond electronic QOPI to a rapid learning system that draws insight from the vast, untapped pool of data on "real world" patients. To meet this vision, ASCO is developing CancerLinQ, our groundbreaking HIT initiative to achieve higher quality, higher value cancer care with better patient outcomes by assembling and analyzing electronic patient information in a learning network. CancerLinQ will help improve the quality of cancer care by:

- Providing real-time quality assessment and reporting based on established guidelines

- Unlocking and analyzing cancer data from multiple clinical sources (e.g., any electronic medical record, pharmacy information, imaging data)
- Delivering personalized clinical decision support to physicians that is tailored to each patient
- Allowing clinicians to gain otherwise inaccessible insights through data mining and visualization

Once the full technology platform is completed, CancerLinQ will place a new universe of practical insights at the fingertips of clinicians who will be able to access information from a massive body of de-identified data on patient care and results.

**Drawing from the Experience of the Oncology Community**

ASCO looks forward to collaborating with you as you work to build a legislative and regulatory framework that protects patients and empowers physicians to use technology. We offer ASCO as a resource to you as you continue the 21<sup>st</sup> Century Cures Initiative to examine how to accelerate the discovery, development, and delivery of promising new treatments to patients. Through our work to develop CancerLinQ, ASCO is learning how the system needs to work for all groups; we are happy to share this expertise with you. With that in mind, we urge you to hold a hearing or roundtable that would include information on oncology clinical care, research, and development. Thank you for the opportunity to participate in this process. Please contact Shelagh Foster at [REDACTED] with any questions.

[REDACTED]

ASCO President



## Association of American Cancer Institutes

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July 22, 2014

The Honorable Fred Upton  
Chairman  
House Energy and Commerce Committee  
2125 Rayburn House Office Building  
Washington, DC 20515

The Honorable Diana DeGette  
Member  
House Energy and Commerce Committee  
2125 Rayburn House Office Building  
Washington, DC 20515

Re: Request for Information Regarding the 21st Century Cures Initiative

Dear Chairman Upton and Representative DeGette:

The Association of American Cancer Institutes (AACI) appreciates the opportunity to submit comments in response to the request for information as part of the Energy and Commerce Committee's 21st Century Cures Initiative. AACI represents 93 of the nation's premier academic and free-standing cancer centers. AACI is dedicated to reducing the burden of cancer by enhancing the impact of the nation's leading academic cancer centers.

AACI thanks Congress for its commitment to ensuring quality care for cancer patients, as well as for providing researchers with the resources that they need to develop better cancer treatments and, ultimately, to find cures for this deadly disease. The partnership between the federal government and our nation's cancer centers is mutually beneficial, and cancer centers continue to make strides in biomedical research thanks to their collaboration with the federal government. Without such support, research projects with the potential to deliver breakthrough therapies would not be possible.

### **What can Congress do to improve the entire digital health care landscape?**

The goal of the National Cancer Act of 1971 was to set our country on a path toward conquering cancer through increased investment in research. Yet, 43 years after the National Cancer Act was signed into law, there is still more progress to be made as the U.S. struggles to maintain its status as the health care innovation capital of the world. Congress has the opportunity to help the U.S. uphold its standing, by improving the digital health care landscape.

AACI cancer centers are at the forefront of the national effort to eradicate cancer. The cancer centers that AACI represents house more than 20,000 scientific, clinical and public health investigators who collaborate in order to translate promising research findings into new approaches to prevent and treat cancer. Making progress against cancer is complex and time-intensive. However, the pace of discovery and translation of basic research to breakthrough therapies could be quickened if researchers could count on a sufficient and predictable investment in federal cancer funding. As research costs and patient need increase, cancer centers continue to depend on federal funding.

The negative effect of flat or decreased funding to cancer research is far greater than the pace of advancements. Without adequate funding, thousands of oncologists and young scientists will conduct their work overseas where adequate funding is available. Cancer centers are the primary source of new discoveries into cancer's causes, prevention, diagnosis, and treatment in the U.S., yet they can only do so much with a constrained budget. In an age where the need for advanced care and public health continues to increase, progress in research can only be made through increased federal funding. Such funding affords the research community the opportunity to advance the digital U.S. health care system.

While AACI recognizes that the Energy and Commerce Committee's 21<sup>st</sup> Century Cures Initiative is not directly involved in the appropriations process, AACI would like to stress to the committee that increased federal funding is a key component to the advancement in science and technology in regard to cancer research and improving the digital health care landscape.

**How can increased utilization of technologies improve patient care? How can Congress ensure such innovation continues while mitigating risks? What needs to be done to create a sufficiently tailored legal and regulatory framework that accounts for the unique nature of these technologies in order to foster continued innovation, reduce uncertainty, and minimize risk?**

AACI and its cancer centers are collaborating on the AACI Molecular Diagnostics Initiative, which is addressing challenges associated with molecular diagnostics, including the development of mutation panels, optimal operation of clinical trials, and data collection. This initiative, introduced by AACI's President, Michelle M. Le Beau, PhD, director of the University of Chicago Comprehensive Cancer Center, underscores the need for innovative new technologies and provides guidance to cancer centers in identifying and addressing obstacles to molecular diagnostics implementation.

Clinical oncology is transitioning from a treatment model based on the anatomic site of tumor origin to a model in which the molecular characteristics of the tumor guide treatment. Targeted cancer therapies are on the rise, requiring the development and implementation of companion diagnostic approaches, identifying patients who may respond to particular therapies. Gene mutations and other predictors allow oncologists to foresee patient sensitivity or response to specific therapies. This is beneficial for both the patient and clinician, but it is still a complicated approach to cancer care.

Technical and practical issues complicate targeted cancer therapies, as tumor heterogeneity, malignant and non-malignant cells and other inhibitors arise. Much more is to be learned and technological advances are within reach. As researchers continue to study single or a limited number of genes, or gene products, the development of new technologies, such as protein and gene arrays, and high-throughput sequencing enables screening of the entire genome for new biomarkers. These biomarkers may better reflect the complex molecular abnormalities within a single tumor that can be exploited for the development of rationally designed therapies. The possibilities are endless, and diagnostic technologies and platforms are progressing quickly.

However, the development of the necessary informatics infrastructure, test standardization and reporting, as well as the integration with the clinical research enterprise, are daunting challenges for cancer centers. Another barrier to advancing personalized medicine is inadequate reimbursement rates for molecular testing through private insurance or Medicare, which does not support the development of molecular diagnostics, or provide incentive for optimization.<sup>1</sup>

AACI's Molecular Diagnostics Initiative is currently drafting a white paper which will include recommendations for action. As Congress continues to seek ways to improve the Medicare reimbursement process and mitigate risk, AACI notes that Medicare has played a large part in cancer centers' ability to help patients fight cancer. Part B coverage under Medicare, which pays for physician-administered drugs and biologics, has allowed oncologists to provide cancer care that is convenient, comprehensive, state-of-the-art and close to home. AACI asks that the Cures Initiative considers the barriers patients and their cancer centers face when seeking therapies and considering alternative reimbursement methods.

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<sup>1</sup> Le Beau, PhD, Michelle M. AACI Commentary, "Precision Oncology Implementation at the Nation's Cancer Centers." Spring 2013, [http://www.aaci-cancer.org/commentary2013\\_03.asp](http://www.aaci-cancer.org/commentary2013_03.asp)

Additionally, AACI recognizes that Congress can ensure that innovation continues in the 21<sup>st</sup> Century by improving clinical trials. Clinical trials in the U.S. should be improved in a way that utilizes and builds upon the innovation and technology existing today. Guaranteeing that all patients are offered the opportunity to participate in a clinical trial, if interested and medically qualified is imperative. According to the American Cancer Society, an estimated 585,000 American are expected to die from cancer in 2014. Only five percent of patients diagnosed with cancer participate in clinical trials, with an even smaller percentage of women, minorities, and underserved patients participating.<sup>2</sup>

Matching a patient with the applicable clinical trial at the appropriate time can be a challenging and time-consuming process for cancer centers. Use of electronic health records (EHRs) to share de-identified patient data can facilitate matching certain patients with applicable studies. Patients can also be matched with trials through biomarkers and identifications in their gene sequence; however, this can also be a costly and lengthy method. If researchers could quickly and inexpensively identify qualified patients in advance, they would be able to provide therapies with greater effectiveness and lower cost for the patient.

**What legal or commercial barriers prevent these technologies from being used on a larger scale at both the point of care and for additional research and development activities? What role can Congress play in addressing them? In the health care setting, are the existing systems to address privacy and informed consent sufficient to protect individual patient interests while facilitating the type of information exchange necessary to ensure the right treatments are prescribed and the best care is provided?**

Under consideration by AACI's Molecular Diagnostics Initiative is a white paper that would include recommendations regarding regulatory and commercial issues surrounding molecular diagnostics and clinical trials. Of particular interest are two challenges: 1) acquisition of medications for patients on trials, and 2) inconsistencies in guidelines for determining when an investigational device exemption is required before a trial can proceed. AACI will be pleased to share the recommendations with the 21<sup>st</sup> Century Cures Initiative when available.

Cancer centers are also battling legal and commercial barriers regarding patient privacy, as institutions work to comply with the Health Insurance Portability and Accountability Act (HIPAA). In January 2013, the Department of Health and Human Services (HHS) published a Final Rule modifying HIPAA's Privacy, Security, Enforcement and Breach Notification Rules in accordance with the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act. Cancer centers continue to ensure that patient privacy is protected and that information is exchanged properly and ethically.

Further progress in technology and thoughtful rulemaking will ensure that patient privacy is protected, particularly when de-identified data are shared. Congressional support for improving clinical trials is vital to ensuring that patients who are qualified for a trial are able to find an appropriate therapy and, when enrolled, that their data are safe. Improved technologies can ensure that patients are engaged throughout their care and that data are collected accurately from beginning to completion of a clinical trial.

## **Conclusion**

AACI appreciates the Committee's 21<sup>st</sup> Century Cures Initiative and its goal of maintaining the U.S.'s standing as the world leader in biomedical innovation. Improvements in the digital health care ecosystem are possible through increased federal funding.

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<sup>2</sup> American Cancer Society. Facts and Figures, 2014.  
<http://www.cancer.org/research/cancerfactsstatistics/cancerfactsfigures2014/>

Please do not hesitate to contact me at [REDACTED] should you or your staff have any questions.

Sincerely,

[REDACTED]

Barbara Duffy Stewart, MPH  
Executive Director



July 22, 2014

Chairman Joe Pitts  
Committee on Energy and Commerce  
US House of Representatives  
420 Cannon House Office Building  
Washington, DC 20515

Ranking Member Frank Pallone  
Committee on Energy and Commerce  
US House of Representatives  
237 Cannon House Office Building  
Washington, DC 20515  
Via [cures@mail.house.gov](mailto:cures@mail.house.gov)

**Re: 21<sup>st</sup> Century Cures—Digital Health Care**

Dear Chairman Pitts and Ranking Member Pallone,

athenahealth, Inc. (“athenahealth”) appreciated the opportunity for our CEO, Mr. Jonathan Bush, to provide oral testimony at the recent Digital Health Care Roundtable as part of the 21<sup>st</sup> Century Cures initiative. These comments reiterate and expand upon that testimony.

athenahealth provides electronic health record (“EHR”), practice management, care coordination, patient communication, data analytics, and related services to physician practices, working with a network of over 50,000 healthcare professionals who serve approximately 50 million patients in all 50 states. All of our providers access our services on the same instance of continuously-updated, cloud-based software. Our cloud platform affords to us and our clients a significant advantage over traditional, static software-based health IT products as we work to realize our company vision of a national information backbone enabling healthcare to work as it should. Our clients’ successes, exemplified by a Meaningful Use attestation rate more than double the national average, underscore the very real potential of health IT to improve care delivery and patient outcomes while increasing efficiency and reducing systemic costs.

As discussed at the roundtable last month, the digital health care tools on the market provide a wide range of solutions to inefficiencies in the current health care system. These technologies can better engage patients in preventative care measures, match patients to clinical trials, deliver more complete patient information at the point of care, and enable a smoother transition to quality-based payment models for physicians, among many other actual and potential benefits.

However, the digital health care market is still in its early stages. There is great risk that its vast potential will not be realized if innovators and entrepreneurs are not encouraged to bring energy,

creativity, and solutions to health care. Many entrepreneurs, particularly ones without significant capital, stay away from health care because of the culture of random regulation and deregulation that prevents the certainty that new businesses and investors crave.

Additionally, regulatory impediments to the open exchange of information in healthcare means that consumers—care providers and patients alike—are effectively prevented from engaging meaningfully in crucial decision-making processes. Put simply, the health care “market” does not function as a true market. Information lock and over-regulation prevent and/or prohibit ordinary consumer behavior and market dynamics, stifling growth and impeding the dynamism that characterizes most of the US economy. These realities more than anything else explain why, a decade and a half into the 21<sup>st</sup> century, a legislative initiative is thought necessary to realize the potential of “21<sup>st</sup> century cures.”

These problems, while significant, can be rectified. As first steps, Congress should: a) create policies that attract and encourage innovators to enter the health care space; b) enact policies that promote the creation of a functioning market for health information exchange; and c) provide incentives for physicians and patients to “shop” for care.

**1. *The regulatory environment should encourage, not impede, entrepreneurs and innovation in health IT.***

Particularly in health IT, too many innovators decline to launch new ventures due to a stultifying lack of regulatory certainty and government-created impediments to innovation. We are encouraged by early signs that the 21<sup>st</sup> Century Cures initiative is systematically evaluating areas where the government can promote health IT innovation, such as by avoiding uncertain or overly-burdensome regulation. The SOFTWARE Act, introduced last year by Rep. Marsha Blackburn (R-TN07), lays the groundwork for a new, predictable oversight framework to ensure the safe development, implementation, and use of health IT without impeding innovation. Another opportunity to spur innovation exists in releasing Medicare claims data, which would allow innovators to leverage that information to create new tools, businesses, and jobs.

**a. *Oversight of health IT should be established via legislation.***

The current regulatory structure applicable to health IT is over-broad, unfocused and anachronistic. It discourages innovation in an industry critical to successfully reforming our health care system. The definition of “device” (21 USC 321(h)), last revised in the 1970s, grants to the FDA broad authority to regulate any “instrumentality” used in the diagnosis or treatment of patients. Functionally, then, the FDA can if it wishes assert virtually limitless jurisdiction over health IT under a statute last revised before any of the technologies in question existed. This is inappropriate and counter-productive in a number of ways:

- The vast majority of health IT is fundamentally different from the medical device technologies that the FDA traditionally and appropriately regulates. Potential patient safety issues associated with the use of health IT, to the extent that they exist, arise in its implementation, customization, and use, not in the manufacturing processes that the FDA appropriately regulates in the devices context. There is no “software factory” for FDA to inspect, and no end “product” for FDA to evaluate. Further, the FDA does not have jurisdiction over the contexts in which most health IT is implemented, customized and used: hospitals, physician offices, and

other care settings. If the square peg of low-risk health IT is forced into the round hole of existing device regulation, then the FDA's laudable efforts to ensure the safety of health IT would be hampered by the inapplicability of their current regulatory framework to the technologies they propose to regulate.

- According to numerous recent publications and statements by FDA officials, the agency's "present regulatory intent" is to exercise "enforcement discretion" with regard to the majority of health IT—effectively excluding many technologies from active FDA regulatory oversight. Although the draft report mandated by the Food and Drug Administration Safety and Innovation Act ("FDASIA") does not use the term "enforcement discretion," the concept is baked into the recommendations and intentions presented in that document. In essence, the authors of the FDASIA report draft propose to maintain for FDA virtually limitless discretion to focus regulatory oversight (or not) at the agency's whim, and asking industry stakeholders (and the care providers they serve) to trust not only that the human beings currently making policy will stick to their own recommendations over time, but that their successors will share that essential perspective as well. This is of inherently limited value, since "present regulatory intent" is non-binding and susceptible to revision at the agency's discretion. Absent legislative action to codify the recommendations of the report, or some variation thereof, the document affords no regulatory certainty whatsoever.
- In our system of government, it is axiomatic that Congress holds the authority and indeed the duty to define the parameters within which regulators regulate. Flipped: a regulatory agency does not have the authority to define for itself its regulatory jurisdiction. Yet under the extraordinarily broad terms of the current governing statute, that is in effect what FDA proposes to do via "enforcement discretion"—define (and periodically redefine) the boundaries of its own regulatory reach.

A common theme heard from Congress, agencies, and industry alike is the need to provide regulatory certainty to foster innovation. In the health IT industry, innovation comes in the form of technologies that iteratively release new versions every month, if not every week. Such technologies—from EHRs to clinical decision support to mobile medical apps—demand a regulatory framework conducive to rapid innovation. Software is not a medical device and should not be subjected to the FDA's onerous device framework (excepting software that controls or is integrated with a medical device, which should of course continue to be subject to the devices framework).

The SOFTWARE Act represents an excellent first step toward defining new statutory categories of lower-risk health IT—"clinical software" and "health software"—and removing those categories from the FDA's jurisdiction. Because the technologies within those categories present low or moderate risk to patients, especially compared to medical devices and software integrated with devices (which are now and should continue to be regulated by FDA under its device framework), the bill instead subjects such technologies to a new oversight framework better tailored to the unique nature of health IT.

The bill would not leave clinical and health software unregulated, nor would it impose burdensome new regulation over clinical and health software that would stifle innovation. The lower-risk categories would be subject to a new framework, appropriately calibrated to their risk profiles to both afford necessary patient protections and protect beneficial innovation in health IT (which itself fosters patient safety). The Committee should continue to work with the framework and definitions set forth in the SOFTWARE Act in the 21<sup>st</sup> Century Cures initiative.

*b. Congress should accelerate the liberation of Medicare claims data.*

The government should provide entrepreneurs access to the tools they need to transform health care. One obvious such tool is the Medicare claims database, and the vast store of invaluable information contained therein. Recent efforts by the Centers for Medicare and Medicaid Services (“CMS”) to make its gigantic dataset more publicly available have been very encouraging. This data truly has the potential to transform our health care system, especially when placed in the hands of innovative providers and technology companies. However, the range of permissible uses and users of CMS data must be broadened to fuel and inform performance improvement. For example, allowing Qualified Entities (“QEs”) under the Affordable Care Act to use CMS claims data in services delivered to health care providers will spur innovation and progress toward better care coordination, population health management, and performance improvement.

Additionally, while no explicit restriction is included in current regulation, CMS regulations and practice reveal a clear bias in favor of non-profits when determining eligibility for QE status. To maximize the benefit of any expansion of permissible uses of claims data, unambiguous language should be included in policy to make clear the QE status is not limited—explicitly or implicitly—to non-profit entities. These changes should be made, of course, with appropriate safeguards against and sanctions for impermissible use or abuse of data. Promoting innovation does not contradict the aim to protect patient health and privacy. Releasing “big data” to the marketplace will give providers and developers the tools to improve care while protecting confidential patient health information.

**2. *The government should remove legal impediments to the open exchange of patient information.***

The 21<sup>st</sup> Century Cures initiative should eliminate barriers to interoperability and information sharing among care providers and their EHRs. Interoperability is critical for health IT to improve care, but there are significant impediments to information flow in healthcare—many of them the unintended consequences of well-intentioned public policy decisions.

*a. The Meaningful Use (“MU”) program as currently structured impedes information sharing by subsidizing technologies that do not share information.*

To-date, nearly 25 billion federal dollars have been spent under the auspices of the MU program administered by the Office of the National Coordinator for Health Information Technology (“ONC”) to subsidize the adoption and “meaningful use” of health IT by care providers. The most common question we are asked by policymakers is why, in light of this very significant expenditure, are so few care providers able to share patient information?

There is a very simple answer to that question: too many of those federal dollars have subsidized the adoption of systems that either cannot or deliberately do not interoperate outside of proprietary vendor platforms, perpetuating the non-interoperable status quo that the program intended to change. There are legitimate market demands for closed information networks in healthcare. If, however, an overriding objective of federal health IT policy is to foster data fluidity and information sharing in healthcare, then at a minimum federal dollars should not be spent to subsidize the acquisition

and use of technologies that cannot or do not enable providers to share information outside of proprietary networks.

Indeed, the same arm of government that disburses those subsidies is now defining as a “hardship” the use of some of the very systems that have been subsidized, to allow providers a mechanism to avoid scheduled reimbursement penalties for failure to successfully attest to “meaningful use” due to vendor failings.<sup>1</sup> A pending rule proposed by the Center for Medicare and Medicaid Services (“CMS”) will continue to actively subsidize old EHR systems that prior rulemakings stated would not be eligible for a subsidy beginning in 2014.<sup>2</sup> To say that fact is a glaring indictment of current MU policy is an obvious understatement.

A few weeks ago CMS released MU Stage 2 numbers, showing that 60% of MU Stage 2 attesting providers so far are athenahealth clients, despite our approximate 3% share of the EHR market, underscoring the simple truth that the technology to meet these standards exists and is available now.

Actual interoperation (as distinguished from the mere capability of “interoperability”) should be a baseline prerequisite for MU certification. Until it is, the federal government will continue to pay for systems that impede one of the few bipartisan, bicameral objectives of health care reform. Current policy artificially distorts the EHR marketplace, providing a taxpayer-funded subsidy for technology platforms that do not meet the basic standards of 21st century information technology, and that absent that market distortion would more quickly be phased out by ordinary market competition.

To compound the issue, beginning in 2015, providers participating in the MU program will no longer have the current option of a 90-day attestation period. This means that participating providers will have to attest to meaningful use of an EHR over the entirety of a 12-month period. Many industry media have prognosticated about a pending “great EHR switch” where providers currently using inferior, non-interoperable platforms will upgrade to modern, interoperable ones. This expectation has been heightened recently by the inability of many vendors to prepare their clients for MU Stage 2, resulting in the “hardship” exemption noted above. However, this 12-month attestation requirement will inhibit the much-needed collective upgrade because a provider desiring to upgrade to a new EHR platform—a process that can take anywhere from a few weeks to several months—will be forced either to forego attestation or the upgrade.

Congress should simplify the MU program to focus on interoperability, reevaluate the certification of systems responsible for the “hardship” exemption, and stop catering to obsolete technologies which delay progress and cannot or do not interoperate. Preventing “silo-ed” information will be even more important when patients start going to different places, such as Walmart, Target, or other clinics for care. In a transitioning system of care delivery, information must become more fluid.

- b. Legal impediments to ordinary market dynamics in healthcare impede information sharing, which in turn stifles innovation.*

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<sup>1</sup> CMS EHR Incentive Program Payment Adjustment and Hardship Exceptions Guidance.  
[http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/paymentadj\\_hardship.html](http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/paymentadj_hardship.html).

<sup>2</sup> CMS rule to help providers make use of Certified EHR Technology.  
<http://www.cms.gov/newsroom/mediareleasedatabase/press-releases/2014-press-releases-items/2014-05-20.html>.

In most every functioning marketplace across the economy, high-quality, curated data is treated as the valuable, innovation-fueling commodity that it is. Market participants in need of data are able to pay fair market value for that data. And those payments are used, in part, to build and maintain the necessary technological infrastructure to enable the efficient, secure exchange of both information and value. This is true everywhere from the banking and online trading systems to the national information network that enables the tracking and exchange of after-market auto parts.

In healthcare, however, because the transfer of patient data occurs most frequently in the context of a care referral any accompanying transfer of value is deemed illegal remuneration under the Stark Laws and/or the Anti-Kickback Statute. As a result, in healthcare the owner/curator of quality data is obligated to assume the cost of electronic transfer of information to a recipient. The beneficiary of the work and the infrastructure investment necessary to curate that data and enable its secure and efficient transfer—the recipient—is literally legally prohibited from paying fair market value for that work and investment. This paradigm, which forces the curator of data to pay for the privilege of sending it electronically to a recipient, operates as a very effective economic disincentive to innovation, investment in technology, and information sharing in healthcare.

Again, the solution to this problem is straightforward: policymakers must recognize that laws intended to prevent fraud and abuse in a fee-for-service world, written before the age of rapid innovation in information technology, are in current practice overbroad in their application and actively impeding desired information sharing in healthcare.

### ***3. Physicians and patients must be incentivized to “shop” for care.***

Across the healthcare industry there is almost universal support for the proposition that we must engage and empower patients to become more involved in their own care. New technologies can enable patients to match themselves to clinical trials or provide health information such as weight or glucose readings to their physicians in real time. However, health care currently lacks the transparency and proper incentives for patients to genuinely engage in value-based decision-making. Patients are typically unaware of the price disparity that exists between equivalent care settings or falsely equate higher cost with higher quality. In almost every other industry from electronics to airlines, American consumers have proven themselves very capable “shoppers” for the highest quality and cost-efficient services. If healthcare could only leverage this marketplace, it could drive down costs and revise systemic inefficiencies.

However, health care decisions can be complex and are often made during emotional or stressful times. Sick patients turn to physicians for assistance in that process, so patient engagement must start with the physician. Physicians should be incentivized and equipped to begin “shopping” for care on behalf of and with their patients, but overly broad regulations, particularly with respect to Medicare reimbursement and fraud and abuse laws, prevent physicians from pursuing creative solutions. If physicians were enabled to take a more proactive role in shopping for care, patients could then be incentivized to partner with their physicians to understand their options and make cost-conscious choices. Technology exists for patients to transform the delivery of their care, but policymakers must encourage and incentivize that transition.

The 21<sup>st</sup> Century Cures Initiative appropriately acknowledges the critical role of digital health in transforming health care. We appreciate the Committee’s willingness to take on digital health policy

issues and the opportunity to provide feedback on this topic. We look forward to working with the Committee and are of course willing to discuss these comments further at your convenience.

Sincerely,



Dan Haley  
Vice President, Government and Regulatory Affairs