BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

July 22, 2014

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

Representative Dianna DeGette
2368 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton and Representative DeGette,

The Blue Cross Blue Shield Association (BCBSA) commends the Energy and Commerce Committee's "21st Century Cures" initiative and appreciates the opportunity to provide input and feedback to ensure that the legal and regulatory framework fosters the development of a digital health care ecosystem. We would like to focus our comments on three areas: (1) Genomics; (2) Telehealth; and (3) a Health IT Roadmap.

Genomics

The committee has noted the importance of genomics to fundamentally transform many aspects of our health care delivery system. We believe it would be timely and important for Congress to address barriers that could impede the clinical utilization of genomic testing.

First, Congress could support better enforcement of regulatory oversight by FDA on genetic testing that would provide transparency related to the analytic validity, clinical validity, and clinical utility of these test. Given the FDA recently required 23andME to stop marketing their tests without such information, it seems appropriate for FDA to require labs to provide information proving the usefulness of the test. Without such information, adoption would be slowed.

Second, we urge Congress to provide funding to NIH that allows modification to the Genetic Testing Registry. Currently, the registry lacks necessary data regarding the elements listed above. With more NIH funding and regulatory oversight by FDA, the registry could be useful for policy determination and clinical decision making.

Third, it is important to address the knowledge gap among practicing physicians. BCBSA is working with NIH and others in a public-private effort, ISCC (Inter-Society Coordinating Committee), to address this knowledge deficit that prevents proper use of genetic testing (see the link http://www.genome.gov/27554614). However, the current budget is limited and may not be sustainable.

Telehealth

As Chairman Pitts stated on May 1, 2014, telemedicine and digital medicine, in all of their forms, present a host of potential benefits to both patients and providers. To provide support for such technologies, and thereby foster and realize the promise of 21st century technologies to improve the lives of Americans, we urge developing a meaningful 21st century definition of telehealth and taking action to help break down the barriers to innovative telehealth solutions, such as out-of-date perspectives that make it impossible to establish a physician-patient relationship via telehealth. To this end, we endorse the recent introduction of H.R. 3750, the "Telehealth Modernization Act," which by providing states with principles when developing policies that govern telehealth, would go a long ways to promoting private sector telehealth innovations. We believe the bill's definition of telehealth and principles to provide guidance to states can form the basis for establishing a solid treatment relationship between the provider and patient, and a reasonable standard of practice for rendering care and prescribing drugs.

Health IT Roadmap

BCBSA and Blue Plans are concerned about the daunting array of health IT rules and requirements on the horizon, which will place enormous demands on scarce IT resources for all stakeholders. A master IT roadmap that sets priorities, dates, and milestones – across all of the competing priorities is urgently needed to ensure implementation can be sequenced in a manner that makes most sense for all stakeholders and to prevent added costs and burdens. This would enable health plans and other stakeholders to plan and budget accordingly and not waste precious resources so the promise of 21st century technologies can be fully realized.

The committee is well aware of the IT demands created by the ACA. Among them: insurance exchanges (the Marketplaces) product filing and approval (SERFF, HIOS), enrollment (issuer direct, FFM based), electronic data maintenance (pre-audit files, data baselining / reconciliation), and financial reconciliation (risk adjustment, risk corridors and reinsurance).

But in addition, health plans face:

(1) A plethora of rules and processes for HIPAA Administrative Simplification. As a result of legislative and regulatory initiatives that modified the original HIPAA administrative standards and broadened the scope of the Health IT infrastructure – primarily the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH Act) and Patient Protection and the Affordable Care Act of 2010 (ACA) – health plans must over the next several years implement multiple new standards and operating rules and identifier enhancements, develop new processes for testing and certifying compliance, and possibly prepare for new HIPAA requirements. Current statutory deadlines are either out of date or no longer rationale in light of all the other demands. Therefore, we recommend that a roadmap lay out a new sequence the HIPAA Administrative Simplification requirements projects in a way that does not overwhelm the engagement of industry resources.

(2) A highly uncertain environment of interoperability standards and initiatives. The federal government has a score or more of initiatives underway, many under the aegis of the Office of the National Coordinator for HIT's Standards and Interoperability Framework, some aimed specifically at health plans (such as the initiative to automate the Blue Button, which may require implementation of new standards for reporting), some of which will affect health plans' participation in public and private health information exchanges, and others which will have significant impacts on providers. The latter raise particular concerns for Blue Plans, because we believe that data must be used in an integrated way to support moving away from volume-

based, fee-for-service reimbursement to arrangements based on value. Plans use data to empower providers, giving them access to the data, tools, funding and analytical expertise they need to effectively and efficiently manage the patient population and deliver the most appropriate care in the most appropriate setting. Taking an integrated approach to conveying data is critical because changing payments alone will not transform care if clinicians lack the means to identify and implement best practices. Therefore, we recommend that a roadmap prioritize existing and needed interoperability initiatives – particularly those at the intersection of relationships between health plans and providers – and lay out clear milestones for implementing new technical standards.

Underlying all these requirements is the imperative for health plans to improve the engagement of consumers, so that consumers have the right amount and level of information to make informed decisions and become more active partners in their health and the management of their care. If health plans are to succeed in engaging consumers with new technologies and data – a pillar of the digital health care ecosystem – a roadmap must provide a way to navigate among the requirements for ACA implementation, HIPAA administrative simplification, and interoperability noted above.

We thank you for considering our comments and recommendations, and would be pleased to work with the committee in any way to ensure a rationale, cost-effective development and implementation of a digital health care ecosystem

Sincerely,

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July 22, 2014

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Representative Diana DeGette
Ranking Member, Subcommittee on Oversight and Investigation
House Committee on Energy and Commerce
2125 Rayburn House Office Building
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RE: 21st Century Cures: Leveraging Technology to Accelerate the #Path2Cures

Dear Chairman Upton and Representative DeGette,

Cerner commends the U.S. House Energy and Commerce Committee for its work to advance health care through the 21st Century Path to Cures Initiative. We agree that modernizing the discovery, development and delivery of cures will lead to higher quality and more efficient care while reducing costs and fostering innovation. We are pleased for the opportunity to provide feedback to the Committee's "Call to Action" white paper.

By way of background, Cerner is the largest standalone health care IT company in the world. With more than 14,000 client facilities worldwide and a presence in 24 countries, we remain at the forefront of health IT innovation on a global scale. Our solution offerings span all hospital departments, ambulatory practices, employer sites and retail pharmacies. In 2011, we adopted the tagline "health care is too important to stay the same."™ This exemplifies our belief that the status quo in health care must change in order to truly improve health outcomes and save lives. The 21st Century Path to Cures Initiative aligns with our belief in promoting innovation at the intersection of health care and technology, which Cerner has been committed to for decades.

Cerner is uniquely positioned to comment on the oversight issues that face the health IT industry and the efforts by government to date to address those issues. The U.S. Food and Drug Administration (FDA) actively regulates certain Cerner solutions as medical devices. As a result, these solutions are subject to the regulations imposed by the FDA under the Food, Drug and Cosmetics Act, which govern the design and development of medical devices, the pre-market clearance of such devices and the post-market surveillance concerning the safety and efficacy of such devices. Other Cerner solutions, including *PowerChart*™, our electronic health record (EHR) technology, are not actively regulated by the FDA; however, our EHR products are certified and tested under the Office of the National Coordinator for Health Information Technology (ONC) Certification Program.

We commend Congress for passing the Health Information Technology for Economic and Clinical Health (HITECH) Act which created many opportunities for the health IT industry. For example, under the Meaningful Use EHR Incentive Program, more than 600,000 eligible hospitals and more than 7,800 eligible providers have attested to date using Cerner's EHR technology, qualifying for millions in incentive dollars. As we evaluate next steps for incentivizing adoption and meaningful use of EHRs, we encourage Congress to support policies that build on the current successes of the program thus far and leverage valuable EHR data to realize transformative innovations in patient care, including personalized medicine, clinical decision support, evidence-based care protocols and advanced payment models.

Further, to continually promote developments in digital health care and accelerate the "path to cures," we encourage Congress to support a legislative and regulatory framework that allows for rapid innovation and adoption

of information technology in the health care sector. Slowed progress in government-sponsored research and development coupled with prescriptive and outdated regulations are counterproductive to advancing the delivery of health care in our nation. Cerner is pleased that the Energy and Commerce Committee understands this problematic issue and is actively pursuing solutions via the 21st Century Cures initiative.

We respectfully submit the following recommendations and comments for your consideration:

Comprehensive regulatory framework

In our recent comments to the FDA, ONC and the Federal Communications Commission (FCC) regarding the Food and Drug Administration Safety and Information Act (FDASIA) Proposed Risk-Based Regulatory Framework and Strategy for Health Information Technology draft report, Cerner encouraged the Agencies to develop a comprehensive health IT framework cognizant of other federal and state laws that may overlap or augment efforts to address patient safety. Statutory and regulatory language to implement the health IT framework may provide value through activities that endeavor to harmonize or reconcile US federal and state laws, at least to the extent that they do not repeat their purpose or focus. Therefore, just as we encouraged the Agencies to collaborate with Congress and the Energy and Commerce Committee specifically on the 21st Century Cures initiative, we urge Congress to work with the relevant agencies to identify opportunities for statutory clarification or modification toward the end goal of a comprehensive oversight framework. Collaboration among Congress and federal agencies will avoid redundancies and ensure that the framework for health IT is streamlined, effective, supports innovation, and above all, promotes patient safety.

Cerner supports current proposals, including legislation proposed by Representative Marsha Blackburn, the "Sensible Oversight for Technology which Advances Regulatory Efficiency" (SOFTWARE) Act of 2013, as well as the draft FDASIA report, that categorize health IT based on the level and nature of risk and which allow for appropriate oversight mechanisms.

Cerner urges Congress and the Agencies to clarify the health IT oversight process with the primary focus to avoid duplicative regulatory oversight of software spanning more than one classification and to ensure each risk category is not defined in such a way that imposes separate and conflicting requirements.

Innovative technology improves the actual practice of medicine

Cerner encourages Congress to adopt policies that will improve the actual practice of medicine and care delivery. Such policies do not require overly prescriptive or process-focused regulations, but instead allow for flexibility and innovation to take place in the market. To create an environment that fosters innovation, we encourage Congress to support interoperability efforts currently underway in the private industry, promote population health management and encourage the development of innovative practices and strategies that will advance the health care industry and the health of our nation.

Support interoperability - Cerner has a longstanding commitment to developing technology that connects systems and people to improve health status. As our Chairman, CEO and Co-founder Neal Patterson has said, "We are committed to enabling data liquidity for every product. We are committed to enabling our solutions to send and receive data in a universal manner. We are committed to putting these principles to work for every system in every venue of care." This year, Cerner was named #1 HIE Vendor by Black Book Rankings in the Private Inpatient/Hospital HIT EHR category and was recognized as the only HIE vendor with a positive trend in client satisfaction ratings in the 2012 best in KLAS awards. 2013 KLAS research noted that Cerner was the highest rated EHR for interoperability and configurability. Additionally, based on a 2012 HIE Market Report by Chilmark Research, Cerner was named as an HIE vendor to have complete, well-regarded service offerings to address all aspects of HIE deployment from strategy to go-live and maintenance.

While Cerner has seen many individual accomplishments in interoperability, one success we are extremely proud of is the result of our collaborative efforts across our industry. In March of 2013, Cerner founded the CommonWell

Health Alliance along with AllScripts, athenahealth, CPSI, Greenway, McKesson and Sunquest. Traditionally competitors, each company realized that for health IT to really work, it must inherently be interoperable. This is why CommonWell's mission is to define and promote a national infrastructure with common standards and policies that include the fundamental components of identity management, record locator, consent management and trusted data access.

At the 2014 Health Information Management Systems Society (HIMSS) Annual conference, we were proud to announce CVS Caremark and MEDHOST joined the Alliance as contributing members. And earlier this month, Brightree, a post-acute care vendor, and MacPractice, an Apple developer that will bring the Apple community, technology and user base into CommonWell, also were added as contributing members. The additions of these companies create the potential to facilitate information exchange across an even broader provider community, the pilots of which already span four geographies ranging from large cities like Chicago to suburban and rural communities of Elkin, N.C., Henderson, N.C. and Columbia S.C.

During the first pilot phase, CommonWell provider participants enrolled more than 15,000 unique individuals, meaning each of these patients has consented to sharing their personal health information among all providers using a certified EHR system developed by a CommonWell member company. These numbers continue to grow as more patients learn about the benefits of sharing their information. The Alliance plans to expand both in membership and into new geographies throughout the upcoming year.

While CommonWell is working toward improving nationwide health information exchange, we feel strongly that patient identification and patient data-matching is crucial to ensuring the right health data is available at the right place, and at the right time. We strongly urge Congress to remove the current prohibition on expenditures related to the study and development of a National Patient Identifier.

Further, due to inconsistencies in various state and federal privacy laws pertaining to sensitive health information such as that protected under 42 CFR Part 2, we ask Congress to revise these laws and remove obstacles to widespread health information exchange. A nationwide, privacy-focused legal framework is needed to create true interoperability across all venues of care and all types of health information.

Cerner's leadership in interoperability does not end with CommonWell. Through our collaboration with hospitals, employers, providers, consumer advocates and Federally Qualified Health Centers (FQHCs), we facilitate more than 150M clinical exchange transactions per month. Data from our EHR is connected to approximately 90% of U.S. state registries, and we are connected to more than 104 EHRs used by 50,000+ unique providers. The 29 Cerner-powered HIEs span the entire country, including urban and rural populations in many regions, as well as the United Kingdom and Australia.

Cerner appreciates and fully supports the ongoing efforts of the Energy and Commerce Committee to advance interoperability and health information exchange quickly and effectively to improve care across the continuum.

Promote population health management **-** Cerner recognizes that the need to reduce health care spending and payments, transfer risk, and provide more care for sicker patients are making a significant impact on the health care industry. New pressures require health care organizations and providers to adopt new goals in order to decrease costs, focus on health and prevention, optimize payments and delivery models, and secure income from an expanded network.

In order to achieve these new goals, hospitals and providers need to know what is happening and predict what *will* happen within their population, engage those they can help, and manage health and care to improve outcomes. Furthermore, applying the same principles to population health that have been successful with hospitals, including predictive algorithms, clinical decision support and an integrated health system will ensure the right care is delivered to the right person at the right time in the right way.

An example that demonstrates the potential of big data and the benefits of innovative new technologies is Cerner's

partnership with Chicago-based Advocate Health Care. Advocate is the largest Accountable Care Organization (ACO) in the U.S. with more than 550,000 at-risk patient contracts. Together, Cerner and Advocate are developing cloud solutions that integrate all of Advocate's data silos, including administrative and electronic health information. This data is used to create predictive models for patient outcomes before they occur- leading to early interventions and reduced hospital readmissions. The Cerner-Advocate readmission prevention model helped reduce penalty payments from 68% of potential at-risk dollars in 2012 to 13% in 2013, saving Advocate approximately $800K. The use of the readmission model to best allocate finite resources and emphasize pre-discharge education for Chronic Obstructive Pulmonary Disorder (COPD) and heart failure as a way to reduce hospital readmissions demonstrates that this innovative partnership improves quality of life while also saving money. For this reason, Congress should ensure that policies are not constructed in a way that limits the industry's ability to innovate in this space. We encourage Congress to become more familiar with the value of population health management as a mechanism to leverage the widespread adoption of EHRs and support new risk-based payment models.

Encourage the development of innovative practices and strategies - Cerner has played and continues to play an integral role in the delivery of health care by providing information where and when it is needed most. As indicated above, the freedom to innovate and partner with various stakeholders in the industry and in our communities has led to better health outcomes and reduced health care spending.

One area in which Cerner is currently innovating and supports Congressional action is antimicrobial stewardship. Specifically, we support two House bills introduced in this Congress pertaining to the development, use, and monitoring of antimicrobial drugs to promote more effective treatment of patients who have infections for which there is an unmet medical need. The first bill, proposed by Representative Phil Gingrey entitled the "Antibiotic Development to Advance Patient Treatment Act of 2013," supports the approval of certain drugs and biological products indicated for use in a limited population of patients to address increases in bacterial and fungal resistance to drugs and biological products. The second bill, proposed earlier this year by Representative Peter Roskam entitled "Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms of 2014," directs the Secretary of Health and Human Services (HHS) to perform various activities in support of new antimicrobial drugs.

Both of these bills underscore the current dilemma of increasing antimicrobial resistance alongside the decreasing availability of new drugs. We encourage Congress to advance legislation that rewards effective antibiotic-prescribing practices and recognizes the value of an expedited FDA drug approval process for limited use in a limited population. We further suggest that this legislation be expanded to emphasize the role of health IT in facilitating such improvements by developing solutions that help clinicians monitor and document recommended antimicrobial therapy interventions that would be more successful and cost-effective in treating infections.

Recognize of the value of telemedicine - Cerner appreciates the inclusion of telemedicine in the 21st Century Cures initiative. We view the definition of "telemedicine" as encompassing all forms of telecommunications and mobile applications that enhance patient-provider communication outside of a provider's office, enable patients to manage their own health, and open new channels of communication between patients and providers. We believe telemedicine should be described in broad terms as it can be used in different ways depending on the setting. Additionally, many forms of synchronous and asynchronous technologies can be leveraged for telemedicine, so policymakers and regulators must ensure the term is not defined too narrowly or legislated too rigidly. An ideal definition of telemedicine is one that includes any technology which connects patients and providers in different physical locations, empowers patients to become and remain active participants in their care, and provides ongoing tailored communication and support. Our ideal outcome is for advanced payment models to emerge that support any mechanism a provider feels is valuable to his/her practice of medicine and patient engagement, and the need for the term "telemedicine" distinction will go away.

Telemedicine is a powerful tool that can transition our health care system from a volume-based, fee-for-service model to one based on value, prospective payments and optimal health outcomes. Such a model encourages using telemedicine and other innovative technologies to optimize care delivery, making it more efficient, effective and affordable. It also supports population health management by increasing access to, reducing the costs of, and improving the quality of care for diverse populations.

Cerner urges Congress to develop a national policy for telemedicine which will resolve the patchwork of state legislation that has created inconsistency and in some cases been counterproductive to the intended goals of telemedicine. We agree with many in the industry that telemedicine can and will lead to better health outcomes while reducing costs and transforming care delivery and are committed to working with Congress, regulatory agencies, and other industry leaders to figure out how to ensure it is successful.

Please do not hesitate to contact me at [redacted] or Amanda Adams, MPA, Health Policy Strategist, at [redacted] if we can provide any additional information or answer any questions. Cerner hopes you find our comments helpful as you continue your work toward advancing 21st century cures and providing opportunities and support for innovation that will improve the health care system in our nation.

Sincerely,

[redacted]

Meg Marshall, JD
Director, Cerner Health Policy

July 21, 2014

The Honorable Fred Upton
Chairman, House Energy and Commerce Committee
United States House of Representatives
Washington, DC 20515

The Honorable Diana DeGette
Member, House Energy and Commerce Committee
United States House of Representatives
Washington, DC 20515

Submitted electronically to: cures@mail.house.gov

Re: 21st Century Cures - Digital Health Care

Dear Chairman Upton and Representative Member DeGette:

The College of Healthcare Information Management Executives (CHIME) is writing in response to the paper, "21st Century Cures – Digital Health Care, Leveraging Technology to Advance the Discovery, Development, and Delivery of Better Treatments and Cures," published June 17, 2014.

CHIME has more than 1,400 members, composed of chief information officers (CIOs) and other top information technology executives at hospitals and clinics across the nation. CHIME members are responsible for the selection and implementation of clinical and business information technology (IT) systems that will facilitate healthcare transformation.

CHIME appreciates the Committee's holistic approach to understanding the digital healthcare landscape. The Committee's questions related to digital health are timely, given the state of health IT policy and the status of key federal programs influencing technology adoption in the delivery of US healthcare. As the nation's premier organization of senior health IT executives, we offer a focused set of recommendations on the need for federal leadership in three primary categories:

- Standards adoption and harmonization;
- Cross-agency alignment and prioritization of digital health; and
- Research and development.

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In the five years following passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act the healthcare industry faces a new set of challenges that demand coordinated solutions – regulatory and legislative. In order to foster a "digital health care ecosystem that serves as a catalyst for the discovery, development, and delivery of new treatments for patients," CHIME encourages lawmakers to focus their efforts, first, on correcting market failures in health IT, and, second, on developing policy options for emerging health IT issues.

For example, the digital health care ecosystem suffers from two acute market failures – the inability of government-certified EHR technology to interoperate and the absence of a national infrastructure to exchange health information. Substantial gains have been made in EHR adoption by US providers since passage of HITECH, and this particular market failure – low EHR adoption rates – has been largely addressed. What remains is the task of connecting these systems and enabling them to integrate disparate data at the point of care.

Beyond the task of guiding implementation of public law, emerging issues related to patient safety and cybersecurity in the digital healthcare ecosystem also present tremendous opportunity for congressional leadership. Congress initiated important policy work with passage of the Food and Drug Administration Safety and Innovation Act (FDASIA), asking for a risk-based regulatory framework for health IT. Once finished, this framework will require close coordination among Congress and the administration to ensure that it promotes innovation, protects patient safety, and avoids regulatory duplication, as intended. Similarly, close coordination will be needed to help the health sector address emerging cybersecurity threats. The National Institute for Standards and Technology's Cybersecurity Framework is an important first step, but the nuances of the health sector will require both congressional and federal agency engagement.

Some of the issues we raise may require closer congressional scrutiny, others may necessitate legislation. Regardless, CHIME urges Committee members to be mindful of being overly prescriptive where technology policy is concerned; consistent with past work in this space, legislation is best focused when it helps agency's manage towards outcomes, rather than dictating nuance that may become obsolete by the time enactment occurs.

We would be remiss not to mention the need for payment reform, perhaps the only area where new legislation is needed. Without a fundamental reworking of Medicare's fee-for-service reimbursement model, Congress can anticipate increased healthcare costs, marginal quality improvements and a declined position among world leaders in healthcare delivery innovation. We supported the glide path described by H.R. 4015 and commend this committee's leadership for working on a plan to fully repeal and replace Medicare's Sustainable Growth Rate. The effort to design a sensible transition away from fee-for-service reimbursement should not be understated, and CHIME stands ready to help solutions-oriented lawmakers understand the technical challenges and opportunities of relying on performance data to determine reimbursement – a transition we fully support.

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CHIME, once again, appreciates the opportunity to provide comments on this important work. The attached document provides detail on how Congress could help ensure fulfillment of the Committee's 21st Century Cures agenda, by addressing key gaps in standards-based data exchange, patient safety, cybersecurity and other areas. In the context of the Committee's questions, we also offer specific thoughts on the multi-agency FDASIA Health IT Report, consent policy and interoperability.

If there are questions about CHIME's recommendations or more information is needed, please contact Jeffery Smith, Vice President of Public Policy, at [redacted]

We look forward to a continuing dialogue with your offices on this and related matters.

Sincerely,

[redacted]

Russell P. Branzell, FCHIME, CHCIO
President and CEO
CHIME

[redacted]

Randy McCleese, M.B.A., M.S., FCHIME, LCHIME, CHCIO
Chair
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Attachment

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Below, CHIME offers recommendations covering three broad areas including, standards adoption and harmonization; cross-agency alignment and prioritization of digital health and research and development. Key recommendations are structured ahead of more detailed discussion in these areas and the Committee's questions are addressed throughout.

Standards adoption and harmonization

Without data standards, the digital health ecosystem will not realize its full potential to lower healthcare costs and improve care quality. To address gaps related to interoperability, Congress should:

- *Urge administration policymakers to re-evaluate and reorient the government's health IT certification program to incorporate or require more robust interoperability testing;*
- *Support administrative efforts and lead policy development around a consistent strategy to match patients with their data; and*
- *Develop an approach to harmonize state-level patient consent laws.*

Background

The passage of HITECH was a watershed moment for the US digital health ecosystem. Congress had never before made such a large public investment to spur adoption of EHRs and lay the groundwork for a nationwide infrastructure for clinical data. Beyond adoption, Congress passed HITECH tasking federal officials to define the "meaningful use" of EHRs. This process has been orchestrated over the course of nearly 60 monthly meetings between two federal advisory committees and countless workgroups. By many measures, the program has been a success to date. In 2013, nearly six in ten (59%) hospitals had adopted at least a Basic EHR system; this represents a five-fold increase since 2008.[1] Physician adoption rates have more than doubled from 2008 to 2013 with 48% of doctors using a Basic EHR system.[2] The market for health IT products has grown dramatically and data is being generated at staggering volumes to fuel future growth in the sector – all thanks, in large part, to the provisions of HITECH. Despite these positive trends, HITECH and the related regulations surrounding Meaningful Use have not yet yielded the kinds of clinical or consumer benefits that policymakers had hoped.

Current State: Interoperability

It would be incorrect to state that exchange and interoperability of health data is completely absent, but failures related to the health IT market and the government program dictating IT product functionality must be addressed. EHR-to-EHR interoperability remains elusive for most providers. Many CHIME members who wish to connect a patient portal module to their enterprise EHR system, for example, must use expensive interfaces, despite the fact that both products are

[1] Charles, D., Gabriel, M., Furukawa, M., "Adoption of Electronic Health Record Systems among U.S. Non-federal Acute Care Hospitals: 2008-2013" Office of the National Coordinator for Health Information Technology, US Dept. of Health and Human Services, May 2014 http://www.healthit.gov/sites/default/files/oncdatabrief16.pdf

[2] Hsiao, C., Hing, E., "Use and Characteristics of Electronic Health Record Systems Among Office-based Physician Practices: United States, 2001–2013," Centers for Disease Control and Prevention, US Dept. Of Health and Human Services, Jan. 2014 http://www.cdc.gov/nchs/data/databriefs/db143.htm

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government-certified. Summary of Care Records required for transitions of care will soon be routinely exchanged, but the information contained in those Summary of Care Records will not likely integrate with existing patient information. A recent study outlines the various errors seen when exchanging Summary of Care Records, which could have grave consequences for downstream patient safety.[3] One key take away from this research is that live exchange of these documents is likely to omit relevant clinical information, increase the burden of manual review for provider organizations receiving Summary of Care Records and increase the likelihood of a patient safety event based on incomplete or inaccurate data.

Several converging factors present federal regulators and congressional leaders with a unique opportunity to address key challenges in the coming months. Specifically, we believe the Office of the National Coordinator (ONC) should reconsider the role and composition of its certification program to address interoperability. Five years following passage of HITECH, there exists an opportunity to make policy decisions apart from the arbitrary deadlines of the EHR Incentives Program and pivot towards the long-term goal of building and supporting a national digital health ecosystem. ONC's certification program was not built in acknowledgement of how technology is developed, tested, implemented and optimized. This has led to a market dynamic that incentivizes data silos, vendor lock-in and rewards developers who are "first-to-certify" rather than a market characterized by usable, safe and mature health IT products.

In so far as certification appears to be one of the government's best tools to assure adherence to technical standards and specifications, we believe the form and function of certification needs to adapt. CHIME has previously recommended that ONC re-tool its certification program to have a specific focus on beta-testing, post-certified performance and live-setting standards adherence.[4] Designing a certification program that more closely resembles the software development lifecycle would have a tremendously positive impact on both interoperability and patient safety. Further, we believe the results from these more robust tests should be made publicly available, to ensure providers know which products are performing well and adhering to standards in the real-world. By reorienting and leveraging its certification program, ONC could help the private/non-profit sector establish a learning health system, characterized by continuous improvement and consistent accountability.

RECOMMENDATION: Congressional action is needed to ensure that ONC dutifully reexamines it certification program and incorporates more robust interoperability testing in future Certified EHR Technology (CEHRT) Edition updates.

[3] D'Amore, J., Mandel, J., et al. "Are Meaningful Use Stage 2 certified EHRs ready for interoperability? Findings from the SMART C-CDA Collaborative" *J Am Med Inform Assoc* doi:10.1136/amiajnl-2014-002883 http://jamia.bmj.com/content/early/2014/06/26/amiajnl-2014-002883.full

[4] CHIME Response to FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework, July 7, 2014 http://bit.ly/1mW9OrB

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Current State: Patient Matching

Despite years of development, no clear strategy has emerged to accurately and consistently match patients with their longitudinal data across different settings of care. A congressional prohibition, barring federal regulators from developing and requiring adherence to standards for a unique patient identifier, has confounded the patient safety issue immeasurably. In the more than 15 years since the prohibition was placed in report language, the healthcare industry has faltered in developing a private-sector solution and federal regulators have been slow to acknowledge the prevalence of dangers posed by inaccurate matching.

The results of a 2012 CHIME survey suggest that swift action is needed to ensure the right data is matched with the right patient.[5] Survey findings suggest that a majority of hospitals are employing unique patient identifiers (64.8%) concurrent with other matching strategies. Of the nearly 65 percent of CIOs reporting use of unique identifiers, over half (58%) are using at least one other strategy – probabilistic, deterministic, biometric, etc. Yet, even with the use of such varied strategies, false negative and false positive error rates are still unacceptably high. While a majority of CIOs believe their false negative and false positive error rates are at or below industry standard, a considerable percentage believe their health records have error rates that far exceed 8 percent. And perhaps more alarmingly, nearly one-fifth of survey respondents said they can attribute at least one adverse event to a patient mismatch within in the last year. This is not only a patient safety issue, but a financial issue as well. Some hospitals have reported spending nearly $1 million a year to match duplicate records and separate records that were erroneously merged.

Unintended injury or illness attributable to patient data-matching error is a considerable, and growing, problem in this era of health information exchange. And with a substantial portion of CIOs involved with HIEs that use differing approaches to data matching, we can expect the inconsistency and variability inherent to healthcare IT systems to persist – and become more endemic – without national leadership and consistent standards.

RECOMMENDATION: Congress should strike the appropriations report language prohibiting advancement on accurately matching patients with their data. For nearly two decades patient safety has been compromised and health information exchange has been hindered due to this prohibition and the private-sector has failed to develop an adequate workaround. At a minimum, Congress should support administration efforts to help identify possible solutions that can address this staggering patient safety issue.

Current State: Patient Consent

Consent policy varies by jurisdiction and personal health information (PHI) type, and similar to most privacy policy, there is no national consent policy. As health information exchange becomes more prominent, the issue of consent becomes a more daunting challenge. How providers capture patient consent preferences, whether health information exchanges have to abide policies such as

[5] CHIME Survey on Patient Data Matching, May 2012, http://bit.ly/1mWa9KU

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opt-in / opt-out, and federal policies (e.g. mental health) are all confounding issues to the topic of consent. Currently, CHIME is unaware of any technical solution or policy approach shared among a majority of providers to capture consent preferences. We know that ONC is leading an initiative called the Data Segmentation for Privacy (DS4P) through its Standards & Interoperability Framework and we know that SAMHSA is working on a solution that could help deal with sensitive PHI. However, these solutions are years away from scaling, from a technical perspective. From a policy perspective, the privacy outcomes sought will never be realized due to the fractured, state-based scheme guiding current policy.

RECOMMENDATION: Congress should lead an open dialogue to help states align privacy and consent policies that enable cross-border exchange of health information in a secure manner; this should include reexamining certain provisions of HIPAA.

Final Thoughts

While a focus on standards may seem overly simplistic, we firmly believe that a more technical emphasis is needed to catalyze new innovations in digital health. The current state will continue to dominate the future, unless federal leadership emerges. Rather than liberating data, for purposes of public health and research that can be used at the point of care, breakthrough technologies will only perpetuate the current environment of data silos driven by legacy systems.

Focusing congressional actions on interoperability will enable the "network effect" benefits of IT to accrue in healthcare the same way it has impacted other sectors of our economy. Specifically, if the federal certification program pivots to focus on core interoperability – including more robust testing for certified products – we can continue efforts to align standards for products already deployed in healthcare settings. Furthermore, this focus will ensure that new market entrants to healthcare do not compete on IT "plumbing," but, rather, on functionality that will add value to care delivery and patient outcomes.

Cross-agency alignment and prioritization of digital health

As the digital health ecosystem continues on a path of convergence, combining data from enterprise EHR systems, traditional medical devices, mobile applications and remote monitoring systems, so too must policymakers integrate and coordinate their efforts. To help agencies further align and prioritize digital health, Congress should:

- *Support and expect cross-agency collaborations, especially among health- and technology-facing offices;*
- *Investigate the legal environment that enables, or hinders, the reporting of patient safety events that involve health information technology;*
- *Ensure that current or future legislation is in alignment with, or improves, patient safety and cybersecurity efforts already underway by the executive branch.*

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Background
Two recent efforts spearheaded by federal agencies have demonstrated a need for multi-agency collaboration to address policy gaps in health technology. The multi-agency effort to produce a risk-based regulatory framework for health IT, required by FDASIA, is a model example. Another example is NIST's work to develop a cybersecurity framework for owners and operators of critical infrastructure. Both were imperfect, but substantive efforts that should inform future congressional actions.

Current State: FDASIA
CHIME supported the general approach and conceptual frameworks outlined in the FDASIA Health IT Report, including the agencies' focus on software functionality.[6] We offered several recommendations, suggesting federal officials:

- Engage with private-sector testing bodies who are developing tools to more consistently test and continuously monitor adherence to standards;
- Identify and incorporate key interoperability tests that have implications for patient safety, especially those related to transitions of care and the management of chronic care;
- Develop, as part of certification, a mechanism to monitor post-market use of health IT in live settings;
- Form a public-private partnership to develop an adaptable process for identifying standards and best practices, especially related to local implementation, customization and maintenance of health IT;
- Understand that different stakeholders have varying degrees of influence on the safety of health IT and should be expected to conform to different levels of rigorous assessments;
- Ensure that providers have an open pathway to report technology failures with implications for patient safety *before* such failures inflict patient harm; and
- Work to bolster a national network of patient safety organizations to help achieve a continuous learning environment.

The role that Congress can play in supporting the agencies' FDASIA implementation should focus on two areas: encouraging and insisting on close intra-agency or intra-office collaboration and the creation of a legal environment to encourage broad reporting of patient safety events by providers and developers. The current environment does not promote such reporting; developers do not have the same safe harbors that providers have to report patient safety events and providers continue to be hamstrung by contractual language imposed by some vendors.

RECOMMENDATION: Congress should investigate barriers to patient safety reporting in an open forum, such as a hearing. This hearing should include technical barriers and legal barriers to reporting potential and de facto patient safety events.

[6] CHIME Response to FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework, July 7, 2014 http://bit.ly/1mW9OrB

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Current State: Cybersecurity

Healthcare is considered by many experts to be one of the least prepared sectors of the US economy to deal with cybersecurity threats. Given the volume of sensitive information being generated by EHRs and being exchanged as part of care delivery, it is imperative that a healthcare-specific strategy be developed quickly. To aid in this effort NIST produced a draft cybersecurity framework in late 2013. The intent was to help the private sector communicate and systematically understand how to mitigate cybersecurity risk. In December 2013, CHIME responded to NIST's Request for Comment on its cybersecurity framework, with the following recommendations:

- All federal agencies engaged in the regulation of healthcare should use a compatible instantiation of this Framework for risk identification, assessment and management.
- Federal regulatory bodies should not use the Cybersecurity Framework to impose more cost and administrative burden on providers.
- By incorporating the Framework into new requirements regulators should seek a balance between flexibility and prescriptive guidance.
- Further, regulators should identify ways to help support under-resourced providers meet new requirements.
- Future iterations of the Framework should consider the inclusion of a risk counterfactual, or a way to determine what the risk of inaction is likely to be.

RECOMMENDATION: Congress has made admirable strides to address gaps in our nation's cybersecurity strategy; however, comprehensive legislation has remained elusive. For this reason, federal agencies have begun the task of addressing gaps. It is vital that congressional action in this area be complementary to agency work, or clearly justify why alternative approaches are superior.

Research and development

Developing a digital health ecosystem as described by the Committee will not be a low-cost endeavor. However, the benefits accrued across the US economy will return public investment many times over. The timeframe over which this value is realized depends entirely on the level of coordination and commitment Congress puts forth. To fully realize its vision for a 21st Century digital health ecosystem, Congress should:

- *Fully fund agencies and offices that oversee health IT and digital health policy;*
- *Focus funding opportunities on:*
    - *Interoperability research, such as SHARP Grants;*
    - *Electronic Clinical Quality Measurement (eCQM);*
    - *Patient Safety Reporting standards;*
    - *Cybersecurity testing and preparedness for healthcare providers;*

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The Honorable Fred Upton
Chairman
Committee on Energy & Commerce
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Washington, DC 20515

The Honorable Diana DeGette
Ranking Member
Subcommittee on Oversight & Investigations
Committee on Energy & Commerce
2322A Rayburn House Office Building
Washington, DC 20515

Re: 21st Century Cures: Digital Health Care

VIA ELECTRONIC DELIVERY

Dear Chairman Upton and Rep. DeGette:

On behalf of Colorado Access and AccessCare Technology and Services, we thank you for your leadership on the House Energy and Commerce Committee, and in particular, your efforts to accelerate the pace of cures through the recent launch of the unparalleled 21st Century Cures Initiative. As organizations committed to ensuring that Coloradoans have access to affordable and quality health care, we share the initiative's commitment to innovation and leveraging technological advances to enhance patient health.

We believe that technology is a significant asset enabling communities to meet the rapidly changing needs of the US health care system. Utilizing technology to deliver health care services has long been effective in empowering patients and engaging in shared decision making. Our own organizations have seen firsthand that when technology is appropriately applied, it can improve the integration of behavioral and medical care and improve access for populations covered by Medicaid, Child Health Plan *Plus* (CHP+), and Medicare in both urban and rural areas.

It is in this spirit that we urge you to consider various policies to promote the broader integration and utilization of technology, including through strategies that treat a patient in their care setting of choice, such as a patient's home:

- Using technology to promote the twenty-first century house call – allowing the patient's home to serve as the originating site.
- Modifying reimbursement guidelines to facilitate access to telehealth and other innovative approaches.
    - We applaud the Center for Medicare and Medicaid Services' (CMS) expansion of reimbursable telehealth services to include those provided within rural census tracts in the calendar year (CY) 2014 Physician Fee Schedule final regulation (CMS – 1600 – FC).
    - We urge support for the agency to finalize its CY15 proposal that would expand Medicare telehealth codes for psychotherapy and psychoanalysis, prolonged evaluation and management services and annual wellness visits (CMS – 1612 – P)]

What Congress can do:

- Congress can lead the effort to establish a flexible national framework that is adaptable to local innovation. Technology often outpaces legal and regulatory processes.
- Maintaining appropriate safeguards for consumers and providers is of the utmost importance, while allowing for flexibility and provider discretion.

Colorado Access is a nonprofit safety net health plan established in 1994. Serving over 600,000 Coloradans on Medicaid, CHP+, Medicare and Connect for Health Colorado, we support Colorado-based solutions to health care reform. Building on existing infrastructure and relationships, the company seeks to meet Colorado's unique changing needs through innovation, flexibility and leveraging local partnerships. AccessCare Technology and Services enables real-time, video-based treatment of health needs in a high-definition environment through a multi-point telemedicine solution. An overview of our new capabilities can be viewed on YouTube, here.

In closing, we thank you for your consideration of our comments, and hope that as these Committee-level and roundtable deliberations progress, you consider us a resource. We look forward to supporting your efforts to expand access and utilization of technology to improve the health of millions of Americans. Should you have any questions or wish to speak on these issues further, please contact Rebecca Kurz, Legislative Liaison, [redacted]

Thank you again for your leadership,

Alexander Vo, PhD
CEO, AccessCare

Jay Shore, MD
CMO, AccessCare

Gretchen McGinnis
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July 21, 2014

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Representative Diana DeGette
Ranking Member, Subcommittee on Oversight and Investigation
House Committee on Energy and Commerce
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RE: 21st Century Cures: Leveraging Technology to Accelerate the #Path2Cures

Dear Chairman Upton and Representative DeGette:

On behalf of the nearly 40 member companies of the Electronic Health Record Association (EHRA), we are pleased to respond to your white paper, "A Path to 21st Century Cures," to provide our perspectives on how technology can be harnessed to advance our nation's healthcare system to be more available and effective for more Americans. EHRA members employ industry experts in the field of health information technology (HIT) with a broad scope of expertise, including physicians, nurses, pharmacists, technologists, and policy experts. These individuals not only represent the EHR software industry, but also interact with and reflect the breadth of the entire health community. This broad perspective reflects the central role that EHRs can play in any healthcare delivery organization as the foundational technology that brings together all the information gathered during a patient's encounter – from demographics to test results, allergies, medications, nursing notes, and digital images – for every clinician with whom the patient interacts, regardless of location.

HIT, particularly through the accelerated adoption of EHRs as supported by the nation's investment in the EHR Incentive program, is a powerful tool that can support the transition of our health system toward a value-based model focused on optimal health outcomes, encouraging innovative technologies to optimize care delivery, making it more efficient, effective, and affordable. Digitized health information enables the connection of patients and providers in different physical

locations, empowers patients to become and remain active participants in their care, and provides ongoing patient-focused communication and support.

Hospital EHR adoption has grown from 72% reporting use of certified electronic health record technology (CEHRT) in 2011 to 94% in 2013[1]. Physician adoption of EHRs, perhaps more significant given financial and technical challenges in that sector, is growing rapidly as well, with 78% of physicians having adopted EHRs as of 2013 according to the National Center for Health Statistics, up from 57% in 2011[2]. Clearly, successful and meaningful adoption of EHRs is high and growing, and the EHR Incentive Program has played an important role in that growth. Given that Stage 1 of the Incentive Program was focused on accelerating EHR adoption, with the stated intention that Stages 2 and 3 would focus on improved quality and outcomes and increased interoperability, we can be optimistic that the US healthcare system will achieve real return on its investment in HIT and provide value to Americans as both taxpayers and healthcare consumers.

As detailed below, the provider requirements and EHR capabilities associated with Stage 2 will enable considerably enhanced interoperability, reinforcing accelerating private sector trends. We have urged that Stage 3 build on this platform, with a primary focus on interoperability.

This growth in HIT adoption and associated digitization, including new ecosystems of connected HIT, will drive important innovations, including personalized medicine, population health management, data analytics, and advanced payment models. The "merit-based" incentive payment system that was proposed earlier this year in the bicameral, bipartisan Sustainable Growth Rate (SGR) repeal legislation provides an excellent example of important reforms that will depend on HIT. Given the critical role that EHRs will play in enabling healthcare organizations to participate in these programs, we urge Congress and the federal government to engage with EHR developers and the broader HIT community to help prepare for and ensure the best use of technology.

Our member companies and clients are doing important work to advance these types of innovations. For example, a variety of pilot programs are showing that EHRs are a critical tool in enabling new value-based payment models, which are founded on evidence- and data-based care management analytics, population health management, and measurement of quality and efficiency. We also note that EHRs can be used to provide near real-time feedback to physicians on the outcomes of their services, months sooner than is feasible with the current reporting systems.

Based on our experiences with the EHR Incentive Program and other federal and state programs, the EHRA has been consistent in its recommendations that regulatory oversight should focus on standards to support broad-based interoperability and alignment of federal quality reporting programs. It is important to note that good progress is being made with regard to interoperability. For example, Stage 2 of the Incentive Program and requirements for 2014 certified EHR technology increase standardization of data transport and exchange with prescribed terminology and data sets.

Regulatory oversight, regardless of its focus, must be informed by stakeholders who have the experience to ensure that requirements are well-designed and practical. New or revised regulations must also be predictable. Our companies and our collective customers – the majority of hospitals and

[1] ONC Data Brief No. 16, May 2014, Adoption of Electronic Health Record Systems among U.S. Non-federal Acute Care Hospitals: 2008-2013, Dustin Charles, MPH; Meghan Gabriel, PhD; Michael F. Furukawa, PhD.

[2] Hsiao C-J, Hing E., Use and characteristics of electronic health record systems among office-based physician practices: United States, 2001–2013. NCHS data brief, no 143. Hyattsville, MD: National Center for Health Statistics, 2014.

ambulatory practices using EHRs in the US – make significant investments based on good faith in the government's guidance and regulatory timelines. For example, the HIT industry and provider organizations spent significant time and money to prepare for the October 2014 switch to ICD-10. Although this work is the foundation of ICD-10 compliance whenever it is required, this change came unexpectedly at a time when many organizations had resource deployment plans in place to meet the initial date, creating disruption and uncertainty. Moving forward, it is essential that policies and requirements be designed and implemented in ways that enable initial plans to proceed on schedule, without the need for costly and disruptive changes in direction or timing.

To ensure that technology developers are able to respond to customers' requests and pursue market-driven innovation, any HIT regulation must not be overly prescriptive. EHRA has encouraged CMS and the Office of the National Coordinator for Health IT (ONC) to take a very focused and prioritized approach to Stage 3 of the Incentive Program based on what we have learned from Stages 1 and 2. This approach will free vendors to meet priorities identified by our customers and reduce the extent to which government requirements supersede customer requested development, impose costs and uncertainty, slow certification and implementation, and hinder usability. It will also enable ONC and CMS to achieve their policy goals, with excellence in implementation, within the limitations of their leaner budgets for managing the EHR Incentive Program and related initiatives.

In general, we believe that new and emerging technologies that enable value-based payments and accountable care should advance in an innovative manner, outside of the EHR Incentive Program (i.e., meaningful use and certification). Some of these new approaches will be part of traditional EHRs and others will not. For example, EHRs provide not only basic reporting on the required measures, but can also enhance the patient experience and reduce costs with integrated care plans, documented interventions, task management, and outcomes measurement/reporting. With specific focus on accountable care organizations (ACOs), EHRs can be leveraged to promote proactive identification and management of high risk patients, align patients with care teams, help care teams coordinate across delivery sites, coordinate care for multiple problems, support real-time decision-making and population surveillance with evidence-based guidelines, and engage and educate patients to encourage self-care, prescription drug adherence, and lifestyle improvement. These capabilities should not be forced into a regulatory EHR construct. We believe that the market will, in fact, produce the right functionality.

The EHRA has encouraged the use of pilot programs to ensure that proposed regulations are adequately tested before they are codified and rolled out on a broad scale. We encourage thoughtful policies that are based on collaboration with HIT developers to test feasibility and practicality of these requirements as well as impact on physician productivity before they are finalized.

Finally, patient safety is, of course, an important consideration in HIT deployment and oversight. We've long held that patient safety is of paramount importance, with shared responsibility among all participants in the healthcare community – physicians, nurses, hospitals, clinics and other clinicians providing care to the patients; software developers and those who implement HIT; and health information exchange (HIE) organizations. EHRA supports the approach proposed in the Food and Drug Administration Safety Innovation Act (FDASIA) draft report, which categorizes HIT based on the level and nature of risk, then applies appropriate oversight mechanisms to ensure that only HIT that represents the greatest risk to patient safety should be regulated as "medical devices" by the FDA. We note that this three-level approach, including limits on FDA regulation of HIT, is reflected in the SOFTWARE bill being considered by your Committee. We encourage Congress to recognize that HIT can be a factor in improving patient safety, and should be considered appropriately for any proposed oversight to ensure that its role in the delivery of care services is well understood before pursuing burdensome regulation.

Representing a key stakeholder group, we look forward to participating in future activities that drive innovative approaches to address the opportunities described in your white paper. We encourage you to leverage our collective, extensive experience in developing and deploying EHRs and other HIT in thousands of healthcare organizations.

Sincerely,

Mark Segal, PhD
Chair, EHR Association
GE Healthcare IT

Sarah Corley, MD
Vice Chair, EHR Association
NextGen Healthcare

HIMSS EHR Association Executive Committee

Leigh Burchell
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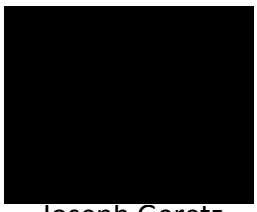

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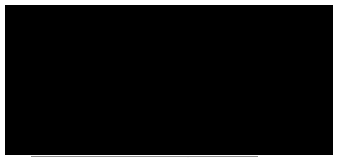

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About HIMSS EHR Association

Established in 2004, the Electronic Health Record (EHR) Association is comprised of nearly 40 companies that supply the vast majority of operational EHRs to physicians' practices and hospitals across the United States. The EHR Association operates on the premise that the rapid, widespread adoption of EHRs will help improve the quality of patient care as well as the productivity and sustainability of the healthcare system as a key enabler of healthcare transformation. The EHR Association and its members are committed to supporting safe healthcare delivery, fostering continued innovation, and operating with high integrity in the market for our users and their patients and families.

The EHR Association is a partner of HIMSS. For more information, visit www.ehrassociation.org.

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July 22, 2014

The Honorable Fred Upton
Chairman
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The Honorable Diana DeGette
Member
Energy and Commerce Committee
U.S. House of Representatives
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Dear Chairman Upton and Representative DeGette:

On behalf of the Board of Directors and members of the Healthcare Information and Management Systems Society **(HIMSS)**, we are pleased to provide observations to you in response to the House Energy and Commerce Committee's 21st Century Cures Initiative request for comments. We congratulate you and the Committee for undertaking this important and timely discussion. HIMSS pledges the commitment and expertise of our organization and that of our members to the goals you have outlined for 21st Century Cures Initiative - "making sure our legal and regulatory framework fosters the development of such 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."

HIMSS is a global, cause-based, not-for-profit organization focused on better health through information technology (IT). HIMSS leads worldwide efforts to optimize health engagements and care outcomes using information technology and health IT thought leadership, education, events, market research, and media services. Founded in 1961, HIMSS encompasses more than 57,000 individuals, of which more than two-thirds work in healthcare provider, governmental, and not-for-profit organizations across the globe, plus over 615 corporations and 400 not-for-profit partner organizations, that share this cause. HIMSS, headquartered in Chicago, serves the global health IT community with additional offices in the United States, Europe, and Asia.

Health IT's role in supporting healthcare transformation in the U.S. is a complex and evolving topic. For the purposes of creating a document that is easy to navigate, we have divided our comments into recommendations, background information, and nine essential areas that should be incorporated into future legislative activity.

I. RECOMMENDATIONS

IT is an essential, foundational element of any meaningful transformation of our Nation's healthcare delivery system. There continues to be widespread, bipartisan support for efforts to move toward an interoperable system that rewards efficiency and quality care

outcomes by enabling providers and patients to access the right information at the right time. In order to realize the optimal transformational benefit of technology for our nation's healthcare delivery system, HIMSS respectfully makes the following recommendations based on our **2014-2015 Public Policy Principles.** Congress should:

a. Make development and adoption of a consistent nationwide patient data-matching strategy through government-private sector collaboration a top priority for the administration. Fund the Office of the National Coordinator (ONC) to complete this high priority task and remove all doubt that, despite previous Appropriations bill language, Congress should support and expect this task to be accomplished in the near future. Accomplish this via passing a clear statement of Congressional intent.

b. Direct the Secretary of the Department of Health and Human Services (HHS) to conduct and publish a review and evaluation of a health IT roadmap of mandated requirements and program changes administered by HHS, which impacts the operations of providers, payers, and health IT vendors.

c. Pass legislation that enables the nationwide realization of the full benefits of telehealth services (e.g.: **H.R.3306**, *the Telehealth Enhancement Act of 2013*), such as the expansion of healthcare access, cost control, and improved quality for rural and underserved populations.

d. Enhance payment models, starting with Medicare, by moving to value-based purchasing and create new payment models in support of the *Patient Protection and Affordable Care Act of 2010's* (ACA) prioritization of health IT.

e. Maintain the flexibility of the *HITECH Act* and the MU Program to ensure that the majority of providers, including small and rural providers, can meet the tenets of the Program, and that our efforts to achieve healthcare transformation do not adversely impact patient care nor the quality of care.

II. BACKGROUND

Enormous Progress Has Been Made to Date

Due to Congressional passage of the *Health Information Technology for Economic and Clinical Health Act of 2009 (**HITECH Act**)*, which authorized the Meaningful Use (MU) Program, this nation has made enormous strides in the past three years in moving toward transforming healthcare through information. According to the ONC, "Hospital adoption of electronic health records (EHRs) systems has significantly increased since the enactment of the *HITECH Act*. During that same period, hospitals' electronic health information exchange with both outside ambulatory providers and other hospitals significantly increased. According to CDC, BASIC hospital adoption more than tripled since 2009, increased from 12% to 44% and CEHRT hospital adoption increased by 18% from 72% in 2011 to 85% in 2012. In 2013, more than six in ten (62%) non-federal acute

care hospitals electronically exchanged laboratory results, radiology reports, clinical care summaries, and/or medication lists with outside providers. This represents a 51% increase since 2008."

HIMSS's research validates these dramatically increasing trends. **HIMSS Analytics** is the authoritative source on electronic medical record (EMR) adoption trends and has devised the **EMR Adoption Model (EMRAM)SM** to track EMR use at hospitals and ambulatory facilities. The EMRAM model scores hospitals in the HIMSS Analytics® Database through an eight-stage model on their progress in moving from a paper-based to a paperless patient record environment. This document provides a snapshot in time of the status of EMRs by states. This analysis is based on hospital level data collected by HIMSS Analytics with the cooperation of individual facilities.

Analysis of HIMSS Analytics' EMRAM^{SM} scale reveals that beginning with the first incentive payments from the Medicare and Medicaid Incentive Program in 2011, U.S. acute care hospitals achieving EMRAM Stage 5 or Stage 6 have increased by more than 270 percent. Stage 7 hospitals – at the most sophisticated, comprehensive level of use – have increased by 181% from Q2 2011 to Q1 2014. Hospitals at the very lowest Stages of 0, 1, 2, and 3 have correspondingly decreased by at least 40%. The HIMSS Analytics EMRAM **scale** is the standard to measure hospitals' adoption of health IT. This data clearly demonstrates that the *HITECH Act* is achieving its intended result of encouraging increased implementation and meaningful use of EHRs among hospitals.

This monumental progress has been achieved in just a little over three and a half years. As a nation, we must stay the course on adoption and focus more attention to provider education, as well as the development of standards that support interoperability and information exchange that enables care coordination.

The Value of Health IT

Private and public investment in health IT infrastructure has had a dramatic impact on care delivery. Using **levels of evidence,** the **HIMSS Health IT Value STEPS™ Model** documents the benefits of health IT across the five categories of satisfaction, treatment, electronic data/ information, prevention and patient education, and savings. The HIMSS Value of Health IT Suite has compiled over 1,200 case studies of demonstrated value, not theoretical value nor anticipated value. These cases demonstrate value including approximately 85% of cases reporting improved safety, quality of care, or gained efficiencies. Increased financial efficiency or operational savings were reported in 65% of the case studies.

Nationwide Healthcare Transformation

Health IT is an essential, foundational element of any meaningful transformation of our nation's healthcare delivery system. These goals can only be achieved by the continued bipartisan support of Congress. Your continued focus on achieving an interoperable

digital system that rewards efficiency and quality care outcomes by enabling providers and patients to access the right information at the right time is essential. The *HITECH Act*, the nationwide adoption of EHRs, health information exchange (HIE), and other health IT will support transformation of American healthcare by:

- encouraging greater patient engagement and empowerment
- reducing errors and improving the quality of clinical care, measurement, and reporting
- supporting essential payment reforms
- promoting safe and private transmission of patient data
- improving coordination of care across all care settings
- enhancing population health management and public health
- guiding clinical decision making resulting in improved healthcare outcomes
- expanding access and improving provider effectiveness
- simplifying business processes, saving resources, and helping control costs
- facilitating dramatic enhancements in research

Optimize the Economic Impact of Heath IT

Health IT supports workforce development in the U.S. and export opportunities abroad. The Bureau of Labor Statistics expects a need for tens of thousands of new health IT jobs over the next decade. Workforce development programs need visibility and tie-in to the Administration's programs on job creation and Congressional support for funding to expand community college, university-based, and non-profit programs. Policymakers must work with the non-profit and business community to launch and support internships, apprenticeships, and fellowships, which provide students and transitioning professionals with real-world experience. In order to expand export opportunities, the federal agencies should work with U.S. companies, healthcare organizations, and non-profit associations to document lessons and best practices from the MU Program and apply them to overseas markets. Additionally, the nation should:

a. Promote the development of a diverse workforce of health IT professionals, clinicians, and educators who understand the requirements of clinical informatics and technology principles through various avenues of career development and levels of education.

b. Continue to authorize and appropriate adequate funding for the Health Resources and Services Administration (HRSA) to promote the proficiency of nursing, clinical, and other healthcare professionals in healthcare technology.

c. Support the addition of health informatics education in accredited schools, develop competency-based continuing education programs, and improve specialty training programs.

d. Support the initiatives and recommendations developed by the Technology Informatics Guiding Education Reform Initiative (**TIGER**), American Association of

Colleges of Nursing (AACN), and Commission on Accreditation of Healthcare Management Education (CAHME). Continue to support the credentialing of health IT professionals, through ongoing development and acquisition of needed competencies to ensure the evolution of the industry, such as Certified Associate in Healthcare Information and Management Systems **(**CAHIMS**).**

e. Support training, transition, and employment of returning veterans, families, and survivors in the health IT professions, which is essential to meaningfully impact the economy, healthcare delivery, and veterans. This includes robust education, training, and mentoring by industry, vendors, providers, and other stakeholders. (As a note, this year HIMSS initiated our Veterans Career Services Initiative to assist our nation's veterans with professional development assistance and employment opportunities within health IT.)

III. HEALTH IT ESSENTIALS

In addition to the identified recommendations, HIMSS offers observations on eight essential areas to advance healthcare IT in support of care coordination and healthcare transformation, including efforts to:

- enhance interoperable data exchange
- promote patient and consumer engagement
- expedite quality reporting alignment
- utilize health IT to update payment models
- coordinate federal health reform mandates
- balance patient safety and innovation
- ensure legislation and regulation maintain pace with technology
- facilitate nationwide telehealth to improve access

We are pleased to provide greater details as follows, as well as have a dialogue with the Committee on these essentials.

1. **Enhance Interoperable Data Exchange Essential to Healthcare Transformation.** The nation cannot realize the full benefits of health information interoperability without comprehensive, consistent data and transmission standards including a common strategy for matching patients with their data. The ability to efficiently and securely exchange health information among healthcare stakeholders is a fundamental requirement to promote patient safety, achieve quality outcomes, and control costs. Interoperability and standardization of data and transmission rules, leading to successful exchange and re-use of health information and efficient and safe clinical workflows, requires the regular updating of standards, implementation guides, regulations, and operating rules. The importance of "adoption and implementation" of the standards is essential to fully realize interoperability.

While there has been substantial progress to date, including development and use of standards and MU Program Stage 2 and its Certified EHR technology, there are also continuing key needs, including patient matching and additional standards development and standardization. Furthermore, unless patients, who can correct errors, provide adherence data, and engage in shared decision making, often making more conservative and cost effective choices, input is integrated into digital health, we will not have the patient as the center of care. Continue investment in the DIRECT Protocol[1] for secure email exchange for all stakeholders including the patient and their designee. Continued investigation on advancing technologies, like open application programming interfaces (APIs) and Open Physician Notes[2], to patients will support and add newer technology to the existing proprietary legacy systems.

In order to continue our progress toward Interoperable Data Exchange, HIMSS emphasizes these essentials:

a. Support the harmonization of federal and state privacy laws and regulations by promoting awareness of the roadblocks to information exchange created by the current differing laws and regulations and conducting hearings on the challenges and possible solutions to mitigate the divergence of federal and state laws and regulations.

b. Develop reimbursement incentives and systems and reduce barriers to providers and patients sharing data, including directing appropriate modifications to the Medicare reimbursement structures to encourage HIE, promote coordination of care, and improve clinical outcomes while helping control healthcare costs. Enhance consistent adoption and development of standards. Overall, keep policy and technologies non-prescriptive and focus on building demand for exchange as a best practice and essential to thrive in new innovative models.

2. **Promote Patient Engagement and Empowerment to Control Costs and Improve Quality.** Patients should play a central and accountable role in their care as a fundamental element of health maintenance, healthcare cost control, and healthcare decision-making of the future. Health information is the fundamental enabler of this personal accountability. Health information must be shared with patients in support of patient-clinician collaboration and individual responsibility for healthcare decisions. Information technologies have and will continue to facilitate patients to receive clear messaging about their clinical and wellness data, healthcare costs and quality, and enable patients to create and sustain behavioral change. Health IT, including EHRs, personal health records (PHRs), electronic health information (EHI), mobile technologies, and data infrastructure, is critical to empowering patients to participate as important and accountable members of their care teams.

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[1] DIRECT Protocol http://directproject.org/content.php?key=overview

[2] Open Physician Notes, http://www.myopennotes.org/

Many patients do not have adequate healthcare literacy and information to engage as full partners in care decision-making. The public needs continuing education, tools, and information to be able to optimally participate. Health literacy programs from HHS (e.g. CMS's Health Literacy Care Model)[3] must be funded and continue to inform and educate the public on topics such as the use of health IT. Initiatives to provide the public with intelligible comparative costs and quality data are essential.

HIMSS emphasizes these essentials:

a. Promote public and private incentives that encourage patient and provider utilization of EHI, while also protecting the privacy and security of individual health information.

b. Continue, on a priority but non-prescriptive basis, development of payment systems that reward providers for shared decision-making, patient-centered care, and better clinical quality outcomes.

c. Encourage public and private payers to make healthcare Portals, PHRs and Payer Based Health Records (PBHRs) available for their beneficiaries that are interoperable with EHRs across the community, using a standards-based health information exchange.

d. Support the use of health IT, portable technologies, and social media to promote consumer awareness, access to data, and health literacy to facilitate participation in healthcare decision-making.

e. Facilitate the innovative development and operation of private and secure interoperable systems that allow patients to view and contribute patient notes to their complete clinical record, as well as control how the information is shared and/or used for secondary purposes.

f. Support and enhance consumer engagement, health literacy, the use of social media in patient education, privacy and security of PHI, and healthcare coordination with publicly-funded and other health programs.

g. Continue to direct patients to incorporate their health IT data into the "apps" of their choice (e.g., Bluebutton+, iBluebutton, FitBit, NikePlus)

3. **Expedite Alignment of Healthcare Quality Reporting Requirements Across All Federal Programs.** Measuring and reporting actual care delivered in accordance with established clinical quality measures (CQMs) is a critical component of any substantive,

[3] CMSs Health Literacy Care Model
http://www.health.gov/communication/literacy/Health_Lit_Care_Model_508.pdf

impactful healthcare transformation effort. Consistent CQMs must be defined nationally against which quality of care delivery can be assessed in order to support necessary quality improvements and cost containment measures.

A major obstacle for the transition to value-based care is a lack of consensus around which CQMs and patient satisfaction measures should be used as proxies to measure Triple Aim goals of quality of care and patient satisfaction. The variety of different measures for Medicare Shared Savings Program (MSSP), Medicare Advantage, and each commercial Accountable Care Organizations (ACOs) results in an overabundance of CQMs that no ACO can present to their primary care physicians (PCPs).

HIMSS emphasizes these essentials:

a. Encourage HHS to facilitate a "clearinghouse" or "resource center" that provides a simple, consolidated communications tool for providers to remain up-to-date on mandated federal quality reporting programs, and a comprehensive roadmap with information on initiatives that affect the health IT community and the providers they serve. Seek private sector and HHS input.

b. Encourage HHS to continue its efforts to expedite and align the EHR Incentive Program's quality reporting requirements across all federal reporting and incentive programs. Align MU Program-consistent CQMs with other health IT compliance initiatives, including Version 5010, International Classification of Diseases, 10th Edition (ICD-10), Physician Quality Reporting System programs (PQRS), and EHR Incentive Program Pilot for Eligible Providers.

c. Create a consensus approach for CQMs consistent with the National Quality Strategy and Plan.

4. **Utilize Health IT as an Essential Element to support Updating Healthcare Payment Models.** Payment models, starting with Medicare, need to continue to be enhanced by moving to value-based purchasing systems and new payment models enabled by health IT. Healthcare payment models must be improved to encourage the delivery of high quality healthcare, help control costs, and promote system-wide sustainability which may include a value-based purchasing, outcomes-based payment, aggregated risk-shifting and shared savings/risk models, bundled payments, capitation, and accountable-care organizations. Congress has already addressed this in the Medicare Sustainable Growth Rate (SGR) legislation and HHS is implementing the tenets now. The role of health IT will also be critical in supporting the success of the Marketplaces in accordance with ACA.

HIMSS emphasizes these essentials:

a. Harmonize health IT regulation as relevant to certified EHRs.

b. Ensure that new payment systems in healthcare reform are coordinated and assisted with health IT.

5. **Coordinate Federal Health Reform Mandates to Mitigate Disruption to Healthcare Delivery.** The ACA, the MU Program, implementation of ICD-10, and various quality measure and reporting requirements are just some of the federally mandated health policy changes and programs impacting our healthcare delivery system at the same time. Many in the healthcare provider community have grave concerns about the unintended consequences, the adverse impact on their practices, and the changes to their relationship with their patients as a result of the cumulative burden imposed by these mandates. Additionally, many of these program changes result in substantial financial outlay for providers, especially small and individual practices. Cumulatively, this impacts the productivity of healthcare delivery.

As the number of federal agencies and programs impacting the healthcare community and healthcare IT continues to increase, each agency focuses on its unique area of interest. At this time, the individual agencies cannot adequately evaluate the distributional impacts of their cumulative actions on providers, patients, and vendors. The result is more than just the accumulation of numerous worthwhile endeavors. The burden on providers and EHR/HIE vendors is greatly exacerbated by the uncoordinated sequential impact of all these various programs and policies. There is a need for a high level of coordination among federal agencies in implementing these changes and programs, such as the health IT incentives, HIE funding, standards, CQM, patient safety, and accountable care/payment reform.

We must be able to accommodate and assist small and rural healthcare providers operating with narrow margins to fully participate in these programs. Additional funding to support the Regional Extension Program, Quality Improvement Organizations, and Community Health Centers should be made available to support this effort.

HIMSS emphasizes these essentials:

a. HHS should conduct and publish a review and evaluation of a health IT roadmap of mandated requirements and program changes administered by HHS impacting the operations of providers, payers, and health IT vendors. The roadmap and evaluation must be updated annually. HHS should facilitate a "clearinghouse" or "resource center" that provides a simple, consolidated communications tool, and a comprehensive roadmap with information on initiatives that affect the health IT community and the providers they serve.

6. **Balance Patient Safety and Innovation with Government Regulation of Health IT Software.** In addition to the nationwide adoption of interoperable EHRs and HIE capabilities, the use and innovation of mobile technologies must be encouraged to expand access to care and patient engagement. Government regulation and oversight play important roles in patient safety, but must be balanced with encouraging technological

innovation. The continued review and assessment of health IT must be conducted in a way that supports patient safety *and* does not impede innovation. Technologies that are widely used in other sectors, and whose functionality does not rely on the variable and unpredictable input of human physiology, should not be classified as medical devices just because they are being used in a healthcare setting.

Regulation and oversight of certain types of health IT should fully reflect the complexity of health information systems as part of a diverse system of care delivery. While health IT plays a significant role in increasing patient safety, IT is only one component of a complex system, and problems with software or technology have the potential to increase safety risks. Regulatory efforts that focus only on one element of a multifaceted social and technical system will lack the necessary holistic approach to enhancing patient safety.

Health IT software and applications, including most EHRs, are used primarily for the subsequent transmission, storage, or management of data by providers. However, they neither fit the definition of, nor would be appropriately regulated as, medical devices. According to their current capabilities, this category includes clinical decision support (CDS) systems. IT capabilities are continually evolving and HIMSS recommends that new policy provide predictable processes for regulation of those health IT products, including how health IT products would move between new and existing regulatory frameworks.

Effective regulation and oversight of health IT is complex and has large potential implications for patient care, healthcare costs, technology innovation, and the economy. The Food and Drug Administration (FDA), Federal Communication Commission (FCC), and the ONC report Food and Drug Administration Safety and Innovation Act's (FDASIA) *Health IT Report – Proposed Strategy and Recommendations for a Risk-Based Framework,* released April 2014, leaves room for subsequent interpretation as technology and situations change.

HIMSS emphasizes these essentials:

a. Support the regulatory framework for health IT software and devices by supporting the FDASIA approach, including that certain devices should not be regulated.

b. Work with the Secretary, HHS, to provide predictable processes regarding the oversight and regulation of health IT products.

c. Ensure that the continued review and assessment of health IT always supports patient safety, protects the provider-patient relationship, and does not impede innovation.

7**. Ensure Legislation and Government Regulation Maintains Pace with Technology.** Health IT, like all technologies, brings about innovative process changes,

but often creates new legal questions that need to be addressed. Our legal and regulatory system must continuously monitor and help support the development of these new technologies and their associated processes by producing clear and articulated enforcement principles that ultimately bring regulatory clarity and transparency to ensure that the community can conform and plan for its future use.

As an example, the rapid nationwide adoption of EHRs as a result of the *HITECH Act*, technological advances in mobile communications, advances in broadband access, and the adoption of telehealth technology and methodologies hold enormous promise for improving healthcare. However, the varying privacy and security regulations that differ from state to state, antiquated healthcare provider licensing regulations, and inadequate healthcare reimbursement schemes are among the roadblocks to fully realizing the benefits of these technologies.

HIMSS emphasizes these essentials:

Administration should set priorities and develop, through a collaborative process between government, industry, healthcare providers, and other health and health IT stakeholders with ample opportunity for public comment recommendations to the Congress addressing the following:

a. Clarify the caregivers' liabilities when relying on EHRs, CDS, patient derived data, and other software and information over which they have no or limited control.

b. Collect, maintain, and use clinical business intelligence (big data).

8. **Facilitate Nationwide Telehealth to Improve Access to Care and Help Control Costs.** The enormous potential of telehealth, or telemedicine, to transform healthcare delivery in America is not being realized due to numerous impediments. These include out-of-date public and private reimbursement structures, inadequate broadband availability, the lack of provider licensing provisions for telehealth across state lines, and varying licensure and practice restrictions between some states. Furthermore, varying federal and state PHI privacy laws and regulations across jurisdictions adversely impact the delivery and quality of care Americans receive via telehealth. In many areas of the country, there are not enough health professionals to provide in-person visits or appropriate follow-up care, especially for mental health and highly specialized services like pediatric critical care. In other areas, distance or unavailability of transportation present impediments to care. Telehealth can be a large part of the solution.

Congress should facilitate the expanded use of telehealth to address access to care issues, control health costs, and improve quality to underserved populations. Rural areas and other underserved populations are frequently subject to poor health quality because of their limited access to care.

HIMSS emphasizes these essentials:

a. Continue to emphasize enhanced broadband access for rural and underserved populations.

b. Address different and sometimes cumbersome state health provider licensing requirements for telehealth across state lines.

c. Update Medicare reimbursement rules that do not support telemedicine.

d. Harmonize varying federal and state privacy laws and regulations pertaining to PHI.

e. Pass legislation that enables the nationwide realization the full benefits of telehealth services. (e.g.: **H.R.3306,** the *Telehealth Enhancement Act of 2013*)

f. Direct HHS to conduct an assessment of available technology that supports telemedicine incentives and, when appropriate, outline pathways to expand and adapt to new technology

HIMSS appreciates the opportunity to share our perspective on some of the many challenges to transforming healthcare in America. We look forward to continuing the dialogue between our members and the Committee to ensure the continued success of health IT as a transformational force in the betterment of healthcare for all Americans. Please address questions to [redacted] HIMSS Senior Director of Congressional Affairs, at [redacted]

Sincerely,

[redacted]

Paul Kleeberg, MD, FAAFP, FHIMSS
Chair, HIMSS Board of Directors
Chief Medical Informatics Officer, Stratis Health
and Clinical Director, Regional Extension
Assistance Center for HIT (REACH)

[redacted]

H. Stephen Lieber, CAE
President/CEO

July 22, 2014

The Honorable Fred Upton
Chairman
House Energy & Commerce Committee
2183 Rayburn HOB
Washington, DC 20515

The Honorable Diana DeGette
Member
House Energy & Commerce Committee
2368 Rayburn HOB
Washington, DC 20515

Submitted electronically to cures@mail.house.gov

Dear Chairman Upton and Representative DeGette:

IMS Health is delighted to have the opportunity to submit input on "Digital Health Care" as part of the House Energy and Commerce Committee (the Committee) collaborative initiative to develop opportunities and ideas to accelerate the pace of cures. As a global leader in information solutions, IMS Health is an international expert in health information stewardship — including privacy and data protection. We firmly believe that:

- Health information used wisely and responsibly advances health care globally and offers real value for patients, payers and providers of health care;
- Patient privacy must be preserved and protected; and
- Data accuracy, validity and interoperability/portability are essential for data to be useful, trusted and lead to health care improvement.

As a company, we are patient privacy and data protection advocates and leading experts in health information collection and analysis. Since our founding more than 60 years ago, IMS Health has pioneered practices to de-identify individual patients' sensitive data, while serving a broad array of health stakeholders, including the FDA and other agencies of the U.S. Department of Health and Human Services. IMS Health relies on a combination of resources, policies and practices to ensure the leadership and expertise necessary to manage information in a manner that balances vital societal values, including improved health care and patient privacy.

Overview:

IMS Health applauds the Committee's 21st Century Cures initiative. This collaboration with private industry, government agencies, thought leaders, experts and law-makers will inform all stakeholders and help identify key issues, policy work and legislative changes that can lead to innovative and effective improvement in our health care system. The 21st Century Cure's White Paper on "Digital Health Care" initiates a vital discussion on transforming health care to a data-driven, information-based system, which is the very focus of IMS Health's business.

As the Committee proceeds with its consideration of data and information exchange, we would like to emphasize the need to prioritize data stewardship and data accuracy in conjunction with data availability.

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We have three overarching comments that are followed by input on the specific questions posed in the Committee White Paper.

1. **Promote the use of patient de-identified health data whenever possible and encourage use of expert review of data use and data practices as a routine data stewardship practice in order to protect patient privacy.**

   Use of de-identified health data, even when combining data from multiple data sets to create longitudinal patient files, is significantly under-utilized by those conducting health care analytics. IMS Health's real world evidence case studies demonstrate that sophisticated analyses on health care performance can be conducted with patient de-identified data, when expert determination methods are used. We urge the adoption of policy that promotes the use of patient de-identified health data, and limits the use of identifiable health data.

   While removal of patient identifiers is an important patient privacy protection, HIPAA standards and guidance for de-identification are clear and note that certain uses of data may also call for administrative, physical and technical safeguards in addition to removal of identifiers. Further, best practices in de-identification require periodic re-evaluation by experts as new data sets become available, data combinations or merges are conducted and analytics advance. In essence, when using large data sets and combining data from multiple sources, use of the expert determination method of patient de-identification is a best practice and its use should be encouraged through public policy on data stewardship and data availability.

2. **IMS Health urges adoption of policies that make data useful before it is disseminated – this includes standards for data interoperability or portability and evaluations to ensure data accuracy.**

   For data to be useful (a.k.a. data utility), it must be portable or interoperable and it must be accurate. Utilization of data sets that do not represent the patient population (e.g., because significant data was not available or the data contributed is inaccurate) has potential to cause significant harm in data analyses by skewing results and leading to inaccurate conclusions. We urge the adoption of policy that provides for data interoperability or portability and review of data for accuracy. Including these preparatory steps for dissemination of data will help ensure that data can be trusted and used for analyses that are in the public interest.

3. **Permit use of Medicare, Medicaid and Veterans Health data by private industry**.

   Medicare, Medicaid and Veteran Administration health comprise a significant part of the nation's health care delivery. The availability and inclusion of data from these programs in analysis to evaluate therapy effectiveness, help curb cost growth and improve quality of care is essential. Current policy prohibits access and use of this data by commercial entities or for any purpose that might be deemed commercial. Access and use of Medicare, Medicaid and Veterans Health Administration data by commercial entities (utilizing patient privacy protections such as de-identification) would allow innovative and essential information analyses that advance patient safety, health oversight, disease management and development of a data-driven health care delivery system. The current policy that prohibits access and use by

commercial entities or for commercial purposes, even commercial purposes that improve health care and health care delivery, stymies our health care system.

Input on Specific Questions Posed by the Digital Health Care White Paper:

***On Mobile Medical Applications and Real-Time Communications with Providers*:**

a. How can the increased utilization of these technologies improve patient care?

An entire continuum of health care needs across the patient journey can be addressed via apps targeted to health care organizations or consumers. These currently fall broadly in the following areas: (1) Diagnosis, (2) Changing consumer/ patient behavior and engagement in health, particularly exercise and diet and (3) Improving the implementation of prescribed treatment regimens (adherence to care and disease management instructions, managing poly-pharmacy or improving medication compliance).[i]

A growing area of app development and use with potential for health quality improvement and cost reduction is the monitoring of changes in patient health status using sensor-to-mobile data transmission (a.k.a. remote patient monitoring). This type of linked mobile application can be a tool for physicians and patients to monitor vital statistics identify risks and complications and manage chronic conditions.[ii] "In the U.S. it is estimated that 5% of the population account for 50% of all healthcare expenditure; 20% of the population account for 80% healthcare expenditure." [iii] Because of this, identifying and preventing negative health events that is the focus of remote patient monitoring is essential to cost reduction efforts.

Diagnosis apps that help physicians to correctly identify patients with rare diseases, especially those who can benefit from newly available therapies, is another area of app development with potential to improve health care delivery. Since doctors are slow to respond to new information (positive or negative) about therapies and can take years to shift their practice in response to new guidelines and new treatments, such mobile diagnostic apps may help speed the time to adoption of best-practices and improve patient care.[iv]

Mobile apps can also change the way patients and their caregivers interact. This includes opening new avenues to improve access to care. By enabling image capture and transmission, mobile apps may enable telemedicine and physician consultation, providing benefits for rural areas. If reimbursement can be established for such mobile patient interaction, then unnecessary physician visits could be avoided and overall costs reduced by enabling engagement with nurse practitioners, physician assistants, pharmacists, nurses and other health care professionals.

b. How can Congress ensure such innovation continues while mitigating risks?

1. Grants for demonstration projects and pilots for the use of mobile applications in the care setting would be beneficial.

   The IMS Institute study, *Patient Apps for Improved Healthcare: From Novelty to Mainstream,* found:

> "few randomized trials have been conducted to determine their [apps] impact and therefore evidence of their effectiveness remains largely anecdotal……..to date there are no public studies published in academic journals or whitepapers which demonstrate effective use of apps for improved compliance. Indeed the only notable results have been released by app developers themselves…..It remains to be seen whether randomized trials of mobile apps for medication compliance can demonstrate a clinical benefit resulting from the use of these tools and hence show their value in the reduction of the multi-billion dollar non-adherence costs to the healthcare system. Such a demonstration of evidence of value would likely drive a surge of apps in this category" and encourage stakeholder adoption. [v]

2. Financial incentives may be needed to encourage application development in areas of unmet need.

   The IMS Institute study of app development found: "Of the 1,980 apps developed to date which relate to specific therapy areas,…the areas of focus of these apps are highly concentrated and not related to leading causes of mortality or non-adherence."[vi] …. It would therefore appear that there is still unmet need in the therapy area space for apps which provide better condition management for patients living with the most disabling chronic diseases, such as cancer, stroke and arthritis. One of the challenges will be how to motivate app developers to address these areas. Although a higher proportion of condition management apps are paid for than, for example, diet apps, only a small number cost more than a few dollars. As such, unless there can be paid content within the apps there is little financial incentive to address these key areas of unmet need and the duty is likely to fall back on pharmaceutical companies or healthcare providers themselves to generate the content." [vii]

3. Apps focused on patient self-diagnosis should be monitored and a professional society accreditation model should be considered.

   While few apps propose of suggest an actual diagnosis to the consumer, it is essential to use with caution with those that do so as not all are connected to a health care provider. Three smartphone apps for melanoma may have serious medical repercussions since they missed melanoma between 30% and 90% of the time according to a report cited in the IMS Institute report, *Patient Apps for Improved Healthcare: From Novelty to Mainstream.* This may have been addressed by the FDA's guidance document on mobile medical apps on September 25, 2013, which "should lead to a higher standard of diagnosis accuracy from the apps, and potentially increase the numbers of apps in this category now that developers have clear guidelines to work within." [viii] Another means to address this would be to incent use of accreditation by physician professional societies to ensure connection to properly licensed health professionals for app generated diagnoses.

c. 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?

The unique nature of mobile medical applications and real-time communications between patients and providers will require flexibility and risk based regulatory frameworks. Approaches to data interoperability/portability and privacy and security must work with the HIPAA and EMR certification frameworks that are already developed.

For data portability or interoperability, IMS recommends the establishment of standards or incentives that would strongly encourage both applications and EMR systems that are intended to communicate information to physicians to be compatible with all widely used data standards. Such **data compatibility and data portability** standards (termed by OMB as open data standards) should therefore apply to new sources of patient medical information such as consumer wearable technologies (e.g., Fitbit, Jawbone UP, Nike+ FuelBand, Misfit, iHealth) and technologies storing medical data such as Patient Digital Health Platforms (PDHPs). Such interoperability requirements could occur under an accreditation arrangement (by a professional society or other private sector qualified entity), as could safety assessments. For instance, "In March 2013 the National Health Service (NHS) Commissioning Board in the U.K. unveiled a library of NHS-reviewed health apps intended to help people manage their health. The apps are produced by a variety of developers and then reviewed by the NHS to ensure they are clinically safe. It is intended to provide an NHS stamp of approval so users know the apps are safe."[ix]

For data stewardship (privacy and security), the non-HIPAA frameworks must be compatible with HIPAA privacy and security standards, and cannot create conflict with the HIPAA standards that covered entities (providers and payers) must follow.

On Increased Data Sharing Through EHRs, Cloud and other Platforms:

a. 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?

Currently, few parties have access to both EMR and claims data sources that are sufficiently robust to conduct the analytics needed to transform health care delivery. When access to adequate EMR and claims data is gained it may pose significant privacy and security concerns. To conduct such work it will be necessary to pool EMR and claims data to create repositories that are representative of the patient population. While in some countries, large de-identified patient EMR and health claims datasets are accessible for analysis by multiple stakeholders to optimize patient care or gain insights into the value of therapies, this is not the case in the U.S. where some health systems pool patient level data for analysis while others, including Medicare, Medicaid and Veterans Health Administration do not.

Concerns about the adequacy of privacy and security protections in cloud environments stop many organizations from embracing this technology, and contracting with cloud providers can be daunting. With continued development of standards across providers, informed by industry input and acceptance, these concerns should lessen.

Further complicating data sharing are challenges of cross-border data transfers and cross-border data use. US-based companies often make use of off-shored resources

and data from outside the US. The ability to access data outside the US can be difficult if a particular country has a data protection law that limits its movement, and this is even more notable in a cloud environment. Many countries are just now determining their position on cloud data storage and whether their citizens' data may legally and ethically be stored in a cloud environment.

While important analyses can be conducted with patient de-identified information, few entities use this technology and the privacy benefits of health care analysis conducted with patient de-identified data is underemphasized. IMS believes and has demonstrated that patient de-identified health information can be used extensively for research and analytics to improve health care. The United States has an opportunity to be a global leader as its HIPAA de-identification guidance and US developed technology and expertise in de-identification offer thought and innovation leadership for global data practices.

Despite the US opportunity to lead on this topic, there is little U.S. leadership. In fact, the very limited access U.S. agencies provide to patient de-identified Medicare, Medicaid, and Veterans Health data, all of which are essential for complete and accurate analyses, undermines the leadership that the HIPAA de-identification guidance offers. It is essential that private entities with excellent data stewardship capabilities be able to access and use patient de-identified Medicare, Medicaid and Veteran's Health information. Such access will develop expertise and leadership in the field of patient de-identification, spur improved data accuracy and utility practices, and develop an important patient population representative data pool.

b. What role can Congress play in addressing them?

Establish incentives and/or requirements to map health data from multiple sources to identify and tap the data needed for a representative sample for an analysis while not creating a large centralized database that raises concerns about privacy, security and data stewardship.[x]

Modify the Qualified Entity program to permit Qualified Entities to collect money/charge for the conduct of analyses that in part use Medicare data. These changes were included in the Energy and Commerce Committee passed Sustainable Growth Rate reform legislation.

Direct CMS and the VA to make Medicare, Medicaid and Veteran's Health patient de-identified data available to commercial entities and permit those entities to combine such data with other data sources as long as such a combination is determined, by experts, to keep the data patient de-identified. The current data use agreements used by CMS contain restrictions that prohibit commercial use AND prohibit data matching which likely will be key to health care improvement and innovation.

On New Technology and Data Shifting Health Care to Predictive and Integrated Health Care Delivery:

a. 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?

HIPAA privacy and security standards, which follow and were based on fair information practices, are well established. Health care delivery is not currently hindered by HIPAA privacy and security standards. Nonetheless, all health care organizations (e.g., providers, plans, clearinghouses and others) would be best served by increasing the transparency of their standard procedures and practices and embracing an accountability model. At the heart of the health care is mutual trust, and any subjective perceptions of insufficiency are likely the result of a failure to be fully transparent and accountable.

Conclusion:

Health care information must be handled with the utmost care. Balancing patient privacy, data interoperability, data accuracy, proprietary concerns and demand for transparency for data driven health care analytics is a delicate, resource-intensive task. Yet it is a task that is at the heart of good data stewardship and that is required of entities engaged in the trusted exchange of health information. In the long run, proper data practices and excellent stewardship will lead to strong and long-standing data practices that will support and enhance patient care in this nation.

Respectfully submitted,

[redacted]

Edward F. Spaniel, Jr.
Vice President, Associate General Counsel

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[i] Patient Apps for Improved Healthcare: From Novelty to Mainstream. Report by the IMS Institute for Healthcare Informatics. The report can be access at: http://www.imshealth.com/portal/site/imshealth/menuitem.762a961826aad98f53c753c71ad8c22a/?vgnextoid=e0f913850c8b1410VgnVCM10000076192ca2RCRD&vgnextchannel=736de5fda6370410VgnVCM10000076192ca2RCRD&vgnextfmt=default

[ii] Ibid

[iii] Aitken, M et al. Healthcare Spending Among Privately Insured Individuals Under Age 65. IMS Institute for Healthcare Informatics, Feb 2012

[iv] Riding the information technology wave in life sciences: priorities, pitfalls and promise. Report by the IMS Institute for Healthcare Informatics The report can be accessed at: http://www.imshealth.com/portal/site/imshealth/menuitem.762a961826aad98f53c753c71ad8c22a/?vgnextoid=743a7a4c18394410VgnVCM10000076192ca2RCRD&vgnextchannel=736de5fda6370410VgnVCM10000076192ca2RCRD&vgnextfmt=default

[v] Patient Apps for Improved Healthcare: From Novelty to Mainstream. Report by the IMS Institute for Healthcare Informatics

[vi] Ibid

[vii] Ibid

[viii] Ibid

[ix] Patient Apps for Improved Healthcare: From Novelty to Mainstream. Report by the IMS Institute for Healthcare Informatics

[x] Riding the information technology wave in life sciences: priorities, pitfalls and promise. Report by the IMS Institute for Healthcare Informatics

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Ann Richardson Berkey

Senior Vice President, Public Affairs

July 22, 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
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Re: 21st Century Cures - Digital Healthcare

Dear Chairman Upton and Representative DeGette:

On behalf of McKesson Corporation ("McKesson"), I am pleased to submit comments to the House Energy and Commerce Committee on the proposed 21st Century Cures Initiative, specifically related to digital healthcare.

For over 180 years, McKesson has led the industry in the delivery of medicines and healthcare products. As the nation's largest distributor of pharmaceuticals, we pride ourselves on the efficiencies that we bring to the healthcare system every day by delivering one-third of all medicines safely and rapidly to pharmacies, hospitals, physician offices, skilled nursing facilities and government locations, including every Department of Veterans Affairs facility, across the country.

As the largest health IT company in the world, we serve the health IT needs of the broadest and most diverse provider base in the industry, including 52 percent of our nation's hospitals, 20 percent of all physician practices and 16 percent of home care agencies, which support more than 50,000 home care visits annually. We process billions of financial healthcare transactions among physicians, hospitals, pharmacies, insurers and financial institutions, and provide care and claims management solutions to most of America's health insurance companies. Through RelayHealth, McKesson's connectivity business, McKesson is connected to more than 90 percent of U.S. pharmacies. We serve as the Centers for Medicare & Medicaid Services (CMS) Transaction Facilitator for the Medicare Part D prescription drug benefit. We manage millions of aggregated personal health records as the leader in connecting patients online with their physicians, hospitals, reference laboratories and health plans and as a participant in community and regional health information exchanges. Our connectivity business enables population and performance management analytics that support new payment and delivery models.

We are actively engaged in the transformation of healthcare from a system burdened by paper to one empowered by interoperable electronic solutions that improve patient safety, reduce the cost and variability of care and advance healthcare efficiency.

McKesson is very supportive of the Committee's interest in developing the 21st Century Cures Initiative during a time of significant opportunity to improve healthcare in the United States. Working together, we can fundamentally transform our healthcare delivery system. Today, our model of care is fragmented and

transactional, where each patient visit is disconnected from the other. We need to move to a model in which care is coordinated across the continuum and populations are managed proactively while optimizing the care of each individual.

Interoperable health IT is foundational to this transformation. Health IT will drive quality improvements, care delivery system efficiencies and, most importantly, improvements in patient experiences. The automation provided by technology will allow us to cost effectively achieve these goals at scale.

McKesson was honored by the invitation to testify before the Energy & Commerce Subcommittees on Health and Communications and Technology on July 17, 2014. We appreciate the opportunity to reiterate our recommendations on the potential for technology to significantly advance healthcare in the 21st century.

First**,** we encourage Congress to ensure the alignment of payment and care models in order to create an environment that fosters interoperability. Coordinated care can dramatically improve the quality, safety and affordability of healthcare, but this new care model must be built on a foundation of interoperable health IT.

Second**,** we recommend that Congress amend the Federal Food, Drug, and Cosmetic Act (FD&C Act) to establish a new risk-based regulatory framework that is specific to health IT. A new framework will foster the development of innovative health IT solutions that will improve care and ultimately transform the delivery of healthcare.

New Care Models for the 21st Century

To transform our care delivery model, we must first solve the challenge of interoperability. Today, our healthcare delivery system lacks a universally adopted, easy, affordable way to allow for the frictionless movement of patient-centered data across all settings of care.

Achieving widespread interoperability requires a multifaceted approach. Over the last few years, industry has made significant progress. Vendors are collaborating and improving their products to offer more interoperable solutions to their customers, and we need to continue to support and encourage this progress. As provider organizations evolve their models to focus on value rather than volume, we must align reimbursement and payment systems to promote coordinated care that is powered by seamless interoperable connectivity. The Office of the National Coordinator for Health IT (ONC) should continue to provide common guardrails for the exchange of healthcare information while providing flexibility within those guardrails to allow for industry innovation.

McKesson supports a collaborative effort among all healthcare stakeholders to develop uniform standards, coordinated policies and the infrastructure necessary to support secure health information exchange to promote interoperability among IT systems. This collaboration will allow for the development of longitudinal patient records across all settings of care and will support the coordination of care between post-acute, long-term, and inpatient settings to proactively prevent readmissions and effectively manage care transitions.

Interoperability is becoming a reality. Automation is here, and efforts to align payment models with care models supported by the exchange of health information will spur the market to innovate and ultimately transform our healthcare system for the 21st century.

Interoperability and CommonWell™ Health Alliance
CommonWell Health Alliance is a current example of innovation and interoperability driven by the private sector. CommonWell is an independent association, founded by McKesson in partnership with our industry competitors, to create vendor-neutral services and standards that will break down the barriers currently inhibiting effective health data exchange. Today, its members include McKesson, RelayHealth, athenahealth, Cerner, Greenway, Allscripts, CPSI, Sunquest, Brightree, MacPractice, MEDHOST and CVS Caremark. CommonWell's goal is to dramatically improve the quality and cost effectiveness of care nationwide by enabling seamless sharing of patient data with the individual's consent, no matter the setting of care.

Currently, services provided by CommonWell facilitate patient consent, identify and match patient records, securely access clinical data in near real-time, and transfer the data directly to existing health IT software systems, regardless of where the care was delivered.

We have made significant progress in 18 months. In the near future, patients will be empowered to manage their healthcare and better utilize new electronic tools to authorize access to their medical history. Technology barriers will no longer constrain who can access a person's record; with appropriate consent, technology will instead support a trusted network for accessing and managing the delivery of the right data, to the right place, at the right time.

Interoperability and Coordinated Care
The military health system provides a good example of the power of interoperability and coordinated care. Since 2009, RelayHealth, a division of McKesson, has provided a patient engagement portal solution to the Defense Health Agency, which includes the joint services of Navy Medicine, Air Force Medical Service, Army Medical Department and the National Capital Region Medical Directorate.

Today, this system manages over one million patient connections to over 25,000 clinical users, including physicians, nurses, pharmacists, medics and corpsmen at every military treatment facility, branch clinic and community-based medical home around the world.

Servicemen and women, retirees, and their families can access this patient portal online to connect to their healthcare teams and records, both inside the military healthcare system as well as with a growing network of civilian healthcare partners. This portal enables them to manage medical appointments, arrange webVisits®, communicate with medical providers and staff, receive alerts for important check-ups or vaccines, request medication refills, and access educational materials on medical conditions or prescriptions. Throughout the world, more than 35,000 new members of the U.S. Armed Forces and their families enroll in this patient portal each month. The service has a 94 percent patient satisfaction rating.

This portal is helping the Military Health System create a stronger patient-centered and coordinated care model to meet their goals of improving the care experience, reducing the per capita cost of care and improving safety and outcomes while ensuring the readiness of the force.

We have the potential to replicate the success of this patient-centered coordinated care model among widespread populations, but we cannot get there without making these innovative solutions interoperable. Patients and their providers must be able to seamlessly access information about the care they receive across multiple care settings.

Health IT Innovation for the 21st Century
Fostering innovation in the private sector is critical to healthcare transformation but there is also a role for Congress to play. Policy changes are needed to reflect current advances in technology and promote ongoing innovation. A 21st century healthcare system demands 21st century policies.

McKesson has endorsed a new regulatory framework for health IT recommended in the Bipartisan Policy Center 2013 report *An Oversight Framework for Assuring Patient Safety in Health Information Technology*. The framework establishes three categories of health IT according to potential risk to the patient and the opportunity for clinical intervention. We believe Congress should amend the Federal Food, Drug, and Cosmetic Act to establish guidelines defining each of these categories of health IT and then oversee federal agencies' implementation of these guidelines. Specifically, the Act should be updated to provide clarity that clinical and administrative software should not be regulated as a medical device.

The *FDASIA Health IT Report* ("the Report"), issued by the FDA, ONC, and FCC in April 2014, calls for a three-category system with FDA jurisdiction focused *only* on health IT that has the highest potential risk, but is silent on whether changes to the FD&C Act are required. As a result, the Report leaves all health IT subject to potential regulation as a medical device by the FDA. We strongly believe that promoting innovation within a 21st century healthcare system will be increasingly difficult, if not impossible, under a regulatory framework that was crafted nearly 40 years ago.

McKesson has endorsed the bipartisan SOFTWARE Act (H.R. 3303), which would create a regulatory framework that recognizes the different categories of health IT solutions and focuses FDA oversight on the technologies that pose the greater potential risk to patient safety. We strongly encourage the Committee to include language similar to the SOFTWARE Act in any legislation that is introduced through the 21st Century Cures Initiative.

Conclusion

To realize a true 21st century healthcare system, we need a fundamental change in our healthcare delivery model. We need to replace a fragmented transactional system with patient-centric coordinated care. This transformation has begun, but we must dramatically accelerate the pace of change.

To do so, we must harness the power of technology. We must align reimbursement and payment models to promote not only the adoption, but also the interoperability of health IT. Congress must also update the law to codify how health IT will be regulated in a way that is predicable and fosters innovation while assuring patient safety. If we are successful, the result will be better outcomes, better access, better cost efficiency and better experiences for patients and their families.

McKesson appreciates the opportunity to share our views on the 21st Century Cures Initiative and digital healthcare. We look forward to continuing to work with you and your colleagues to transform our healthcare system through the development and use of technology. Should you have any questions or need further information, please contact Joe Ganley, Vice President of Federal Government Affairs, at [redacted]

Sincerely,

[redacted]

Ann Richardson Berkey