July 22, 2014

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

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

Re: **21st Century Cures—Digital Health Care**

Dear Chairman Pitts and Ranking Member Pallone,

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

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

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

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

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

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

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

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

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

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

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

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

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

- According to numerous recent publications and statements by FDA officials, the agency's "present regulatory intent" is to exercise "enforcement discretion" with regard to the majority of health IT—effectively excluding many technologies from active FDA regulatory oversight. Although the draft report mandated by the Food and Drug Administration Safety and Innovation Act ("FDASIA") does not use the term "enforcement discretion," the concept is baked into the recommendations and intentions presented in that document. In essence, the authors of the FDASIA report draft propose to maintain for FDA virtually limitless discretion to focus regulatory oversight (or not) at the agency's whim, and asking industry stakeholders (and the care providers they serve) to trust not only that the human beings currently making policy will stick to their own recommendations over time, but that their successors will share that essential perspective as well. This is of inherently limited value, since "present regulatory intent" is non-binding and susceptible to revision at the agency's discretion. Absent legislative action to codify the recommendations of the report, or some variation thereof, the document affords no regulatory certainty whatsoever.

- In our system of government, it is axiomatic that Congress holds the authority and indeed the duty to define the parameters within which regulators regulate. Flipped: a regulatory agency does not have the authority to define for itself its regulatory jurisdiction. Yet under the extraordinarily broad terms of the current governing statute, that is in effect what FDA proposes to do via "enforcement discretion"—define (and periodically redefine) the boundaries of its own regulatory reach.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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[1] CMS EHR Incentive Program Payment Adjustment and Hardship Exceptions Guidance. http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/paymentadj_hardship.html.

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

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

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

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

3. Physicians and patients must be incentivized to "shop" for care.

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

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

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

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

Sincerely,

Dan Haley
Vice President, Government and Regulatory Affairs