January 29, 2016

311 Arsenal Street
Watertown, MA 02472

Senator Lamar Alexander
Chairman, Senate HELP Committee
455 Dirksen Senate Office Building
Washington, DC 20510

Senator Patty Murray
Ranking Member, Senate HELP Committee
154 Russell Senate Office Building
Washington, DC 20510

Re: athenahealth Comments on the Senate HELP Committee Bipartisan Legislation to Improve Health Information Technology for Patients and Families Discussion Draft

Submitted via electronic mail to: HealthIT@help.senate.gov

Dear Chairman Alexander and Ranking Member Murray:

athenahealth appreciates the opportunity to comment on the Committee's discussion draft of bipartisan legislation to improve health information technology for patients and families ("discussion draft"). The discussion draft addresses many issues regarding the use of health IT and exchange of health information, and we commend the Committee's attention to these areas.

As you know, we provide electronic health record ("EHR"), practice management, care coordination, patient communication, data analytics, and related services to physician practices and hospitals, working with a network of over 72,000 healthcare professionals in all 50 states. All of our providers access our services on the same instance of continuously-updated, cloud-based software. Our clients enjoy an ever-increasing level of connectivity to the rest of the healthcare ecosystem, conducting 7 million transactions daily with over 55,000 trading partners, through over 177,000 interfaces and 175 application program interface ("API") endpoints. As actively participating members in multiple private sector interoperability initiatives, including the CommonWell Health Alliance, Carequality/the Sequoia Project, and the Argonaut Project, we see in real time the considerable progress that is being made to connect care across the entire continuum.

We appreciate that the discussion draft is the result of many months of work during which the Committee heard from stakeholders across the entire healthcare industry, many of whom have for too long dealt with an unacceptable lack of interoperability that ultimately increases systemic cost and puts patients at risk. This is an issue that requires attention and swift resolution, and the Committee has set the appropriate goals in

attempting to reduce the burden of federal incentive programs, streamline requirements and processes, and accelerate progress toward a fully interoperating healthcare system.

We are skeptical however, that these goals to simplify and streamline can be achieved through 68 pages of legislation that, while well-intentioned, are fraught with potential unintended consequences. The similarly well-intentioned Meaningful Use ("MU") legislation placed the government too directly in the middle of the nascent health IT market, producing many unintended consequences, disrupting normal market functions, and ultimately contributing to the problems that the Committee is now trying to solve. This lesson should remain at the forefront of the minds of the entire industry as we seek to accelerate information exchange and reduce the burdens of EHR use.

As currently drafted, the approach taken in the discussion draft risks stifling the increasing amount of innovation in health IT. It is simply no longer true that the private sector is failing to interoperate. Huge progress has been made in recent years toward the bipartisan goal of an interoperable healthcare system, without any government involvement whatsoever. Congress must resist the impulse to "solve" yesterday's problem in a way that could very well squelch the solutions that are already well into their evolutions.

Given the rapid progress being made by health IT vendors through collaborations like the CommonWell Health Alliance and Carequality, government should avoid the impulse to mandate a federal "solution" to interoperability. A major barrier to information sharing that existed when the Committee began this process—the lack of a trusted exchange framework—was solved by the private sector through Carequality mere months before this discussion draft was finalized. There is perhaps no greater piece of evidence that the industry needs continued evolution of private sector initiatives, not heavy-handed government intervention through duplicative certification and government-led standards setting processes. Congress should instead focus narrowly on barriers to information sharing that the private sector cannot alone solve, such as information blocking and privacy and security laws.

Finally, we urge the Committee to reject the notion that government certification can convene, coax, or even coerce progress and innovation. True technological progress comes when it is incentivized, usually by market demand, not when it is mandated. Certification of health IT can play an important role in informing consumers, providing transparency, and ensuring a consistent baseline of functionality, but it sets a floor, not a ceiling. The MU certification process is burdensome and diverts limited resources away from meeting customer demands. While this may be justified in certain instances, we ask that the Committee recognize that this burden hinders innovation and ensure that any additional certification requirements that it proposes are in fact necessary and justified.

It is with this context that we provide the following specific comments on each section of the discussion draft:

Section 2 – Assisting Doctors and Hospitals in Improving Quality of Care for Patients

- We support the effort to reduce administrative burden on physicians and commend the Committee for their attention to this issue. However, we are concerned that the intention of this section is unclear and as written implies that the government should intervene in the design of EHRs. While HHS absolutely should endeavor to reduce the burdens on physicians created by well-intentioned programs like MU, it should not be in the business of regulating the usability of EHRs. Section 13103(a)(1) on page 2 requires that HHS reduce the regulatory or administrative requirements "relating to the use of electronic health records," which implies that HHS will work on reducing the burdens of EHR use generally. We suggest that it should read "relating to federal incentive programs or requirements for the use of health information technology," and that language change should be carried throughout subsequent sections.
- athenahealth does not support the proposal to create certification requirements for specialties, which we believe is based on the false premise that new certification requirements will bring developers to the table and fuel innovation to satisfy unmet health IT needs of certain specialties. Certification is a burdensome process that deters investment in health IT and, when mandatory for market entry, diverts development resources away from responding directly to the needs and requests of clinician clients. Responding to consumer demand is a basic operation in a functioning market. Government should not attempt to calculate and implement consumer demand by acting as a surrogate for physician requests of HIT vendors.

Section 3 – Transparency Ratings on Usability and Security to Transform IT (TRUST IT)

- athenahealth does not support the inclusion of TRUST IT. Adding a new layer to an already overly burdensome certification process will only stifle innovation in health IT. We believe that there is a disconnect between the goal of Section 2 to reduce administrative burdens on providers and tremendous burden placed on health IT developers through additional certification criteria in this section. The goal to reduce administrative burden should apply to health IT vendors as well.
    - athenahealth would support the intent of this section *if* it was part of a reform of the MU certification process and leveraged existing private sector ratings systems. We do support added transparency in certification and empowering health IT purchasers with better information with which to compare EHRs. This is a basic activity of a well-functioning market. However, without any changes to existing certification, TRUST IT adds expense and diverts valuable resources away from addressing physician requests for system improvements. Further, Congress requested a study

from HHS on the feasibility of a mechanism to rate EHRs in the Medicare Access and CHIP Reauthorization Act of 2015. It should respect its own process and wait for the recommendations of that report before designing a heavily bureaucratic ratings mechanism.
    - An attestation that health information can be exchanged through an API or successor technology (page 10) is overly prescriptive and not appropriate for legislation. This provision should focus on the desired outcome—information exchange—while remaining technology neutral. athenahealth does support that certification require attestation of no information blocking and the removal of gag clauses to promote transparency (page 9).
    - athenahealth does support a hardship exemption and establishment of a fund to aid providers whose health IT products are decertified by ONC. Currently, hardship exemptions are left to the discretion of CMS. We believe Congress should require CMS to provide them to all providers whose EHR product has been decertified. Providers should not be held responsible for the failure of health IT vendors.

Section 4 – Information Blocking

- Information blocking is a major barrier to the free flow of health information. We appreciate the HELP Committee's attention to the issue, and recommend the following adjustments to the language as proposed.
    - The knowledge standard of information blocking for providers and HIT developers should be consistent. Specifically, Section (1)(B) on page 22 defines information blocking as when a developer "knows or should know" or when providers "knowingly and unreasonably" restrict information exchange. This variance incorrectly implies that information blocking is more directly an issue caused by developers than providers. Based on our experience and analysis of unsuccessful system integrations, information blocking is often a combination of developer and provider policies and decisions. In order to effectively deter such behavior, the entire ecosystem should be held to the same standard.
    - OIG jurisdiction should cover the entire healthcare industry, not just health IT developers, on page 24. The proposed language potentially excludes labs, registries, HIEs, and industry collaborations from information blocking penalties, yet all of these entities could engage in the behaviors that this section aims to address. We recommend that the Committee should aim to deter information blocking consistently for the entire health care ecosystem.
    - We support the limitation of liability on page 26 for health IT developers that make information available based on a good faith reliance on advice from the Office of Civil Rights. However, we suggest that this protection should be extended to all entities that may exchange information,

including providers, labs, registries, HIEs, and industry collaborations. Just as the entire ecosystem should be held to the same standard with respect to information sharing and blocking, the entire ecosystem should also be afforded the same protections.

Section 5 – Interoperability

- We do not support the creation of the HIT Advisory Committee or the HELP Committee's focus on establishing standards, a "network of networks," or a trusted exchange framework. We strongly recommend striking all of these sections, especially those placed in brackets. Section 7 creates burdensome requirements where scalable private sector solutions to interoperability already exist, which risks impeding, rather than fueling, these solutions.
    - Congress should not attempt to create a trusted exchange framework, not because it is not needed, but because it is already being provided by the private sector. Carequality has already established a successful, evolving framework, and any government action risks conflicting with or stifling those efforts. Additionally, past proposals of ONC's Nationwide Health Information Network for a government led framework were repeatedly rejected by stakeholders. The Committee should avoid creating a framework and allow the private sector momentum to continue in this space.
    - athenahealth does not support the creation of the HIT Advisory Committee and we strongly oppose its focus on recommending standards for interoperability. Standards and technology are not a major barrier to interoperability. For real progress to continue, Congress must distance itself from the notion that it can convene all stakeholders and coerce progress. The past 4 years of MU provide ample evidence that bringing stakeholders to the table does not spur innovation. Establishing 3 and 5 year timeframes to convene stakeholders to review and adopt new standards illustrates an inherent problem with government attempting to "create" innovation. Innovative solutions do not occur on pre-defined timeframes. If implemented, the HIT Advisory Committee recommendations and time frames will keep entrepreneurs tethered to the pace of government, far behind the pace of innovation in the rest of the information economy. Additionally, as drafted, the Advisory Committee is to recommend only standards that have been developed, harmonized, or recognized by itself (page 40). Government will best serve the industry by removing itself from setting standards and allowing the private sector to drive development, maturity and adoption. The Committee's attention should focus directly on removing barriers and incentivizing the desired outcome, not mandating a laundry list of things desired in health IT.

- The interoperability definition (page 27) should focus on the ability to exchange and use information. We recommend striking "without special effort" from the definition. Identifying what establishes "special effort" is purely subjective, problematic, and unclear. We also recommend including the concept of authorized exchange in the definition and suggest that the language read "…has the ability to securely exchange electronic health information, where authorized…"
- athenahealth disagrees with mandated use of a single provider directory. Congress should understand that a provider directory is not a pre-requisite to actual interoperability. There are successful networks today, such as the CommonWell Health Alliance, which function without a provider directory because the patient is at the center of care. If a government funded electronic provider directory is built, we urge the Committee to make its use optional. An optional directory will address a need for some vendors and allow other networks to function without one or adopt an alternative private sector solution.

Section 6 – Leveraging Health IT to Improve Patient Care

- athenahealth strongly supports the inclusion of health IT developers in the definition of "provider" under the Patient Safety and Quality Improvement Act. For health IT to continually improve and promote better quality and improved health outcomes, developers must be able to learn from each other's successes and, more importantly, mistakes. This requires a safe space that is designed to promote open dialogue and dissemination of lessons learned. Patient Safety Organizations (PSOs) can uniquely provide this environment. The inclusion of health IT developers in the PSO framework will go a long way toward providing a pathway for continual improvement in the safety and usability of health IT.

Section 7 – Empowering Patients and improving patient access to electronic health information

- We applaud the HELP Committee's attention to patient access. However, athenahealth does not support adding patient access standards to the certification process. We believe that existing information blocking requirements in the legislation accomplish the intent of patient access certification requirements. Additionally, it is often unclear how privacy and security laws should apply to rapidly evolving information exchange use cases. Further education on what is permitted and clarification how certain privacy and security laws apply to various situations will reduce instances where such laws become barriers to information exchange. However, we recommend that if Congress truly is committed to removing barriers to interoperability, it needs to address the patchwork of inconsistent and sometimes conflicting state laws on privacy, security, and patient consent.

- As currently drafted, the provision on page 61 regarding certifying usability for patients is duplicative and potentially conflicts with earlier sections. We would support this type of provision *if* the sections on TRUST IT and the creation of the Health IT Advisory Committee are removed.

Section 8 – Encouraging trust relationships for certified EHRs

- We appreciate the Committee's recognition that trust and security of health IT is often a red-herring excuse to not share information. This is yet another area where the private sector has made considerable progress. We urge that any government action to encourage trust relationships build on that progress, incorporating for example the trust framework created by the Carequality Interoperability Framework and following the approach employed by the CommonWell Health Alliance.

Section 9 – GAO Study on patient matching

- We appreciate that Congress is finally addressing patient matching and moving past the long-standing moratorium on the topic. However, we urge the Committee to recognize that the lack of a viable patient matching program is already being addressed by the private sector, faster and more effectively than government resources can. Currently, the CommonWell Health Alliance and Sequoia Project achieve high rates of successful matching. Further, the College of Healthcare Information Management Executives (CHIME) recently launched a National Patient ID Challenge to award $1 million to a scalable solution that privately, accurately, and safely confirms a patient's identity 100% of the time. The winner will be announced in early 2017. In light of the substantial recent progress, we urge that any government initiative on this topic be designed to complement, not supplant or duplicate, private sector progress.

Sincerely,

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athenahealth, Inc.