March 13, 2015

athenahealth

311 Arsenal Street
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The Honorable Michael C. Burgess, M.D.
US House of Representatives
2336 Rayburn House Office Building
Washington, DC 20515

Submitted via electronic mail to: James.Paluskiewicz@mail.house.gov

Dear Dr. Burgess,

I appreciate the opportunity to comment on behalf of athenahealth, Inc. on the recent discussion draft of a key section of the 21st Century Cures legislative package, sub-titled "Ensuring Interoperability of Qualified Electronic Health Records" ("the Draft"). As a company and as individuals we are dedicated to the vision of a national health information backbone that enables healthcare to work the way it should. Too many federal health information technology policy initiatives and programs aspire to mediocrity, setting goals and timelines that will, at best, leave health information technology lagging years behind the levels of functionality we all take for granted in the rest of our continually-evolving information economy. We commend you and your colleagues for raising your sights in formulating the Draft, proposing a reasonable framework and workable, private sector-oriented mechanisms to radically accelerate progress toward 21st century information-sharing in the U.S. healthcare system.

As you know, athenahealth provides electronic health record ("EHR"), practice management, care coordination, patient communication, data analytics, and related services to a network of more than 60,000 healthcare professionals who serve over 60 million patients in all 50 states. We envision and work to establish a nationwide health information backbone to connect patients and care providers with the information they need to seek and provide high-quality, cost-effective, efficient care. All of our providers access our services on the same instance of continuously updated, cloud-based software. 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.

"Interoperation" vs. "Interoperability"

Our comments begin with an important semantic distinction: In our view federal policy should strive for "*interoperation"* (an activity) in healthcare, not mere "*interoperability"* (a capability). Much of the confusion and dysfunction that exists in this area of health IT policy arises from the fact that vendors of closed information systems are able with straight faces to claim that their systems are *interoperable*,

while in practice they erect financial, operational, and technological barriers to actual, systemic *interoperation*.

We are very pleased that the Draft seeks to identify, require, and measure *actual interoperation*—patient and provider-authorized information exchange—between and among the many disparate health IT platforms in use today and in the future. We urge you to adopt explicitly this semantic differentiation throughout the Draft (especially in defining "widespread interoperability" on Page 23), to make clear Congress's intention to require actual information exchange, not merely a theoretical exchange capability. The former will radically transform the care delivery and payment systems in this country. The latter would barely alter today's unacceptable status quo.

On a closely related note, we commend you for resisting the understandable impulse to mandate adoption and use of specific technical standards for interoperation in healthcare. We believe that this intention is clear and unambiguous throughout the Draft. Such a mandate would result perversely in yet more stagnation in healthcare, as innovation inevitably progresses beyond the limits of our current collective imaginations. More, it would ensure that the historically change-averse health IT industry would innovate to that soon-to-be-obsolete standard, and no further—an outcome that, again, would allow vendors to truthfully lay claim to "interoperability" while doing little or nothing to enable systemic interoperation. As the early success of the CommonWell Health Alliance demonstrates beyond dispute, cross-platform interoperation is not only possible without a technical standards mandate, it is *occurring in the present tense*. If passed into law the Draft would do much to encourage participation in models like CommonWell, enabling compliance with the requirements of the Draft without imposition of undue costs on care providers.

A Three-Tiered Conceptualization of Interoperation

We suggest that interoperation can rationally be conceptualized in three tiers, allowing for policy recognition of the unfortunate status quo and steady, incremental progress toward the goal of catching health IT up to the rest of the information economy and enabling it to keep pace with innovation thereafter. Crucially, policy should be structured in a way that enables continual innovation and evolution even beyond what we can envision today. We are very pleased that the Draft fits that characterization.

Tier 1 interoperation is confined to intra-organization information sharing, enabling the exchange of demographic information, clinical orders, and lab results within the four walls of a single hospital or health system. Developed and achieved years ago, this is the rudimentary level of interoperation needed to solve a very specific, pre-internet problem: the lack of communication between departments in a single care setting, using wired connections and local networks—a paradigm long dead in most industries but still prevalent in healthcare. The standards for intra-organization interoperation, developed by the organization Health Level Seven

International ("HL7") are well established and sufficient for their limited purpose, but incapable of servicing the interoperation needs of the wider healthcare economy.

The Draft's establishment of measures for interoperation, an enforcement mechanism, and potential sanctions for behaviors that impede interoperation will push our industry to evolve more quickly and uniformly past this outdated paradigm.

Tier 2 interoperation, which can be described as patient-centric and provider-directed information exchange, will allow for inter-organization sharing of the entirety of a patient's information by enabling seamless transitions of care across care settings and care provider organizations. The barriers to achievement of this limited goal are not technological. To achieve it, two things must happen.

First and foremost, health systems and vendors must accept widespread interoperation as a prerequisite of doing business in the health IT sector. The Draft would effectively force such a condition to participation by requiring and measuring actual interoperation, and applying sanctions for deliberate information blocking that would fall appropriately on the heads of health IT vendors that do not facilitate interoperation and provider organizations that use information lock as a deliberate means to control patient populations.

Second, vendors must agree upon and implement technical standards and practices sufficient to actually enable patient-centric exchange, including for single sign-on, patient matching, and patient consent. Contrary to conventional wisdom in Washington, DC, *this is already happening*. Through organizations like the CommonWell Health Alliance, many major health IT vendors and their care provider clients are much further along the road to functioning tier 2 interoperation than was the case a mere year ago, and will be further along yet in the near future. Members of CommonWell are already exchanging information. Members track patient consent to have their information shared through CommonWell, match patient identities across disparate health IT systems, and then make patients' longitudinal medical records available to all providers, regardless of health IT platform. Other organizations are developing means to achieve the same results. By foregoing mandated standards and focusing appropriately on desired outcomes, the Draft will accelerate this ongoing evolution.

Even if it is widely achieved in the near term, however, tier two interoperation will still leave healthcare lagging significantly behind the rest of the information economy. **Tier 3 interoperation,** which should be the open-ended goal of federal interoperation policy, is the open platform. Virtually non-existent in healthcare today, this type of information exchange is prevalent in other sectors where open application program interfaces ("APIs") are used to seamlessly weave together data from multiple disparate systems. Amazon, Kayak, Google Maps, and Mint, for example, all use APIs to pull data from multiple other systems and sources, but

users only see a simple interface and user-friendly experience that presents all required information in one place. In healthcare, open platform interoperation will eventually enable an EHR to use APIs to integrate with countless other systems beyond just other EHRs: scheduling services like ZocDoc, or patient genome sequencing services like 23andMe, for example. Healthcare providers and patients will have the "one-stop shopping" experience that is standard in other industries but currently all but nonexistent in healthcare. Crucially, the Draft will allow for and in a very real sense require continuous innovation in health IT—innovation that has been effectively stalled by the perverse incentives created by current health IT policy.

Specific Comments

Subject to and informed by the above general comments, we offer the following specific comments and proposed minor revisions and clarifications to the Draft:

"Authorized user"

We anticipate patient privacy-focused objections to the current language of the Draft. Fortunately, we believe many of these objections can be addressed simply by making clear at the outset that every requirement established is informed by and consistent with over-arching HIPAA requirements and state privacy laws. Despite the profound need for much greater information sharing in healthcare, it goes without saying that data access and information fluidity cannot and should not be absolute. Patient data must be accessible at the direction and discretion of the appropriate access mediator: the patient and/or, where legal and appropriate, the authorized care provider. To establish a patient-centric model of interoperation, "authorized user" should mean any person who has a patient's consent to view his or her health information or is otherwise permitted to use or disclose a patient's protected health information under HIPAA.

The Draft's use of "authorized users" without further explanation further risks confusion (perhaps deliberate confusion) between patient/provider authorization (permission), and system authorization (along the lines of a technical OAUTH or SAML authorization, to enable validation of credentials—and thereby authority—across platforms). The language should not inadvertently allow vendors or their clients to set up extra-legal barriers to "authorization" that have the effect of inhibiting legal, clinically-indicated information sharing.

Today, too often decisions about data access and accessibility are functionally delegated to health IT vendors, who create technical and financial barriers to electronic information exchange that cannot be overcome by the patient or the care provider. This reality effectively takes the decision to share or not share information away from the patient and vests it in an inaccessible and unaccountable (and often unknown) corporate actor.

The following changes would achieve both of the above objectives, clarifying and emphasizing the legal authority and ability of patients and care-givers to direct the sharing of data, and requiring vendors to enable actual exercise of that authority by prohibiting deliberate technical barriers to access.

Page 1:

"(1) OPEN ACCESS.—The record allows authorized users access, to the extent allowed under federal and state privacy laws and consistent with patient consent, to the entirety of a patient's data from any and all qualified electronic health records without restriction, including technical systems restrictions that limit access or authorization to designated individuals or organizations.

Single sign-on

We believe that the reference at Page 1, line 18 to "such as sign-on systems" is intended to require single sign-on functionality, effectively prohibiting systems designs that require care providers to log into multiple discrete systems in order to achieve authorized access to/sharing of patient data. We applaud and agree with that goal, but believe that "such as sign-on systems" is ambiguous and confusing. To achieve the intended objective the Draft should make clear that, in addition to not requiring providers to log into multiple systems, qualified records systems must make available the entirety of a patient's information to other qualified record systems through a standardized technical interface to allow for semantic consumption by other qualified records. Qualified records should have a single endpoint/hub infrastructure via which other qualified record systems can access data for any patient record that is associated with any healthcare organization. We suggest the following revision:

Page 1:

"(2) COMPLETE ACCESS TO HEALTH DATA.—

The record ~~allows~~ provides authorized users of other qualified electronic health records access to the entirety of a patient's data through a standardized technical interface ~~in one location~~, and allows authorized users to access the entirety of a patient's data that resides in other qualified electronic health records in one location, without the need for the user to utilize multiple user interfaces or applications. ~~(such~~

~~as sign on sys-~~

~~22 tems).~~

Information Blocking

In our view the term "information blocking" is misleading in that it overstates the case against technological and financial barriers to active interoperation and by virtue of that overstatement risks overlooking prevalent barriers to information sharing. "Information impediments" is more precise, because often those barriers are less absolute blocks to information sharing than functional and/or financial impediments and/or disincentives to information exchange. A new framework that prohibits absolute barriers to exchange (which are rare) but does not address functional and financial impediments will fall short of the objectives of the Draft. We suggest:

Page 2

"(3) DOES NOT BLOCK ACCESS TO OTHER QUALIFIED ELECTRONIC HEALTH RECORDS.—The record does not prevent or materially discourage, including through the use of preferential or differential pricing or pricing that exceeds fair market value, end users from interfacing and exchanging information with other qualified electronic health records.

This suggested edit is intended to get at the frequent business practice of discouraging or effectively preventing out-of-platform information exchange by charging an unreasonable premium for the construction of an out-of-platform interface, imposing unreasonable additional per-patient or per-transaction costs for out-of-platform information sharing, or both. To level the field and incentivize information sharing whenever it is desired and/or clinically indicated, pricing should be uniform regardless of whether sharing is in-platform or out of platform, and should not exceed fair market value for the infrastructure and services required to effectuate the sharing.

"Method"

We are aware of concerns expressed by some stakeholders that the Draft's use of the word "method," without definition, is untenably vague and ambiguous. In light of the many obligations placed on care providers by largely unaccountable advisory bodies as the Meaningful Use program evolved, this is by no means a misplaced concern. To the contrary, however, we believe that subsection 3010(b), read in its

entirety, represents appropriate Congressional deference to the collective presumed and expected subject matter expertise of the Charter Organization, and establishes appropriately flexible guidelines for the Charter Organization to develop and prescribe workable means by which to measure and assess the outcomes directed by the Draft (actual interoperation), whether by some attestation and audit framework or otherwise. Establishing such methods via statute, or even severely constraining the ability of the Charter Organization to prescribe (and revise) them, would run counter to the overall intention of the Draft to establish flexible, private-sector-based means of achieving and then maintaining actual interoperation in healthcare. The fact that under the terms of the Draft the Secretary will have the final authority to adopt (or not) and "methods" so prescribed by the Charter Organization will guard against regulatory overreach by that Organization.

Attestation and Decertification

We have long contended that the core failing of the Meaningful Use program was the decision at inception to impose penalties on care providers for unsatisfactory outcomes controlled by their vendors. This decision led directly to much of the understandable provider and provider advocate opposition to the progression of the program through its subsequent stages, as each new stage increased the impact of vendor failings on their provider clients. For the framework proposed in the Draft to succeed, it is crucial to avoid repetition of this policy failing, and to impose sanctions on the party(s) responsible for non-compliant outcomes. We believe that the Draft largely succeeds in this regard, but could be marginally clarified and strengthened.

First, in response to question 9 circulated with the Draft, we emphatically believe that vendors as well as providers should be required to attest to their compliance with the information-blocking provisions of the Draft. Our understanding is that vendors of qualified EHRs are required to do so on page 15, line 3, and that the OIG is authorized to investigate such claims on page 17, line 23. If that is not the case, we do believe that vendors and providers should be required to make the same attestation that they are not engaging in prohibited conduct, since so often information exchange is blocked (deliberately or inadvertently) by vendors and providers working in tandem.

More broadly, providers and their advocates are understandably concerned that the decertification mechanisms in the Draft will inadvertently leave them again holding the bag for the failings of non-compliant vendors. As a company dedicated to servicing care providers we are sympathetic to that concern.

We hasten to note in this regard that any vendor could quite easily and cost-effectively achieve the capability to meet the requirements of the Draft simply by joining the CommonWell Health Alliance (or any similar initiative). As vendors' customers, care providers have considerable leverage to encourage such a move. Even so, many providers and provider organizations will likely call for some variety

of safe harbor or protection to be included in the Draft, to protect providers from the impact of sanctions, like decertification, imposed against their vendors. We support those calls in principle, but suggest that any safe harbor or protection should create an incentive to the impacted provider to take tangible steps to upgrade to technology that is compliant with the crucially important provisions of the Draft.

In closing, I and my colleagues at athenahealth commend you for recognizing the need to focus federal health IT policy on the outcomes that are uniformly desired and supported across the political spectrum, in Congress and in the Administration, inside Washington and across the country. Interoperation to enable information fluidity is a crucial pre-condition to broad care coordination, which is itself an indispensible element of healthcare reform of any meaningful variety.

We believe the Draft represents an important shift in the interoperation policy conversation, and look forward to working with your office first to improve the excellent first draft, and then to encourage its passage into law. Thank you again for the opportunity to share our point of view.

Sincerely,

Dan Haley
Vice President
Government and Regulatory Affairs