

April 2, 2015



Sylvia Mathews Burwell
Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building Suite 310G
200 Independence Ave., S.W.
Washington, D.C. 20201

311 Arsenal Street
Watertown, MA 02472

Karen DeSalvo, MD, MPH, MSc
National Coordinator
Office of the National Coordinator for Health IT
Hubert H. Humphrey Building Suite 729D
200 Independence Ave, S.W.
Washington, D.C. 20201

Submitted electronically via www.healthit.gov

Re: Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap

Dear Administrator Burwell and Dr. DeSalvo:

athenahealth, Inc. ("athenahealth") appreciates the opportunity to provide comments on the Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap ("Roadmap").

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 ("MU") attestation rate more than double the national average (98.2 percent of athenahealth's eligible providers successfully attested to MU Stage 2) underscore the very real potential of health IT to improve care delivery and patient outcomes while increasing efficiency and reducing systemic costs.

Prefatory Comment: Market-driven interoperation is happening

The entirety of our comments is subject to and informed by observation of a crucially important fact: the market is currently engaged in the process of solving 'the interoperability problem,' achieving results far beyond what was possible even a year ago. Via a number of private sector, non-compulsory associations, the health information technology ("health IT") industry is responding to ever-increasing market demand for interoperation by establishing voluntary mechanisms and standards to enable inter-platform information sharing. One such effort, the CommonWell Health Alliance, is enabling actual cross-vendor interoperation a mere two years after its founding at HIMSS 2013. More such efforts will surely follow this evolution from talking about interoperation to actually enabling it, as the market adapts and responds to the realization that actual interoperation (as opposed to merely theoretical "interoperability") is not only possible, but beginning to happen. Such initiatives are born entirely independent of

government involvement. They are neither mandated nor funded by any government agency. They operate voluntarily, by consensus, without need for federally mandated technical standards, governance structures, plans, or road maps. athenahealth and countless smaller, early-stage health IT companies, many of which are part of our More Disruption Please program, are building themselves to serve an interoperable healthcare system—not because we expect the government to create one, but because we have confidence in the inevitability of market evolution toward that end state. The oft-repeated assertion that the market has 'done nothing to solve the interoperability problem' is simply and demonstrably false. As the Roadmap contemplates out a broad framework for a sustained, government-centric effort to address interoperability, recognition of this baseline fact is crucial.

While we applaud ONC's enhanced focus on interoperability, we would prefer that ONC articulate clear national priorities and unambiguous goals, rather than establish new standards and governance structures to prescribe specific industry actions that might or might not be the best, most efficient means of reaching those goals. Industry is on track to achieve systemic interoperation long before the prescriptions set forth in the Roadmap could reasonably be expected to take hold—especially in light of federal health IT policy's well-established track record of repeated delay and dilution. We are concerned that the Roadmap strives to achieve by a date years in the future a level of basic functionality in health IT that if achieved *today* would still leave health IT lagging as much as a decade behind the information technology in use across the rest of the economy. Its highly-prescriptive approach could easily have unintended consequences that end up impeding rather than encouraging the progress being made by the private sector, much as the low certification bar set for the MU program unintentionally created an artificial market for non-interoperable technology platforms.

Despite that low bar, it must be acknowledged that the MU program succeeded in vastly accelerating adoption of information technology in healthcare. The government (and the taxpayer) would be best served at this point by stepping aside to let the seeds it has sown sprout and bear fruit.

If government must continue to intervene in the health IT market, efforts going forward should focus on outcomes, not means

The Roadmap's current, standards-based approach will not solve the interoperability problem, and could even exacerbate it. While technical standards are necessary to share information electronically, they are not sufficient to remove common barriers to interoperation, most of which are structural and/or financial, not technical. The 'state of the art' in information technology is continually evolving, so standards must be flexible and susceptible to continued evolution and replacement. Mandated standards could effectively freeze the current, unacceptable health IT status quo in amber, resulting perversely in yet more stagnation in healthcare as innovation inevitably progresses beyond the limits of our current collective imaginations.

More, mandated standards would virtually ensure that much of the historically change-averse health IT industry will innovate to those soon-to-be-obsolete standards, and no further. Such an outcome would allow vendors to truthfully lay claim to "interoperability" while doing little or nothing to enable systemic interoperation, just as today vendors lay claim to certification for "meaningful use" while failing to enable—or even impeding—interoperation.

As noted above, we believe strongly that the shortest route from today's unacceptable status quo to tomorrow's interoperating health IT system follows the path already being trod by private sector organizations like CommonWell. If the government must intervene in support of

greater interoperability, however, it should do so in a deliberately limited way, by broadly defining the desired outcome(s) (actual, systemic interoperability in healthcare) rather than via prescribed standards. Flexibly defining interoperability will allow for private market-based measurement and evaluation of industry and provider organization behaviors, which will in turn allow for identification of impediments to the desired behaviors and appropriate market reaction to those impediments. The situational awareness afforded by such a regime would do more to push the health IT industry toward an interoperable baseline for market participation than any standards mandate could.

Interoperability should be defined flexibly, allowing for continuous evolution

We suggest that the evolution from today's unacceptable disconnectedness to systemic interoperability can rationally be staged 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. Those tiers, as we conceptualize them, are:

Tier 1—*intraoperability*. Developed and achieved years ago, this is the rudimentary level of location-based 'interoperability' necessary to solve a very specific, pre-internet problem: a lack of communication between departments in a single care setting, using wired connections and local networks to enable intra-organization information sharing such as exchange of demographic information, clinical orders, and lab results within the four walls of a single hospital or health system. This paradigm is long buried in most industries but still prevalent in healthcare. The standards for intraoperability, developed by the organization Health Level Seven International ("HL7"), are well established and sufficient for their limited purpose, but incapable of servicing the interoperability needs of the wider healthcare economy. The fact that HL7 standards are still frequently referenced in the interoperability policy conversation is as good a measure as any of just how backward looking that conversation has to-date been.

The Roadmap acknowledges the barriers that are impeding progress beyond this first tier of interoperability, but it does little to propose how to quickly and effectively break down those barriers. We suggest that the Roadmap should outline private sector-oriented mechanisms to measure actual interoperability and highlight and/or sanction behaviors that impede interoperability. This will help push the health IT industry to evolve more quickly and uniformly past the outdated tier 1 paradigm.

Tier 2—*interoperability*. The second level of information sharing might be described as patient-centered and provider-directed information exchange. Still relatively rare in healthcare, this paradigm allows for inter-organization sharing of the entirety of a patient's record by enabling seamless transitions of care across care settings and care provider organizations. The barriers to achievement of this limited goal are not technical. To achieve broad achievement of this still rudimentary level of interoperability, two things must happen:

First and foremost, health systems and vendors must accept widespread interoperability as a prerequisite of doing business in the health IT sector. Again, market pressure is moving the health IT industry inexorably in this direction. The best and most productive approach in our view would be for the government to step back and allow this evolution to continue.

Government could use the comparatively light touch of its status as a dominant consumer of health IT services to accelerate this process by endorsing private sector-based mechanisms to measure actual interoperability, conditioning participation in federal programs on demonstration of actual interoperability, and/or sanctioning deliberate information blocking

by health IT vendors that do not facilitate interoperability and provider organizations that use information lock as a deliberate means to control patient populations. However in our view primarily non-governmental macroeconomic forces that will continue to exert themselves with or without further government intervention are driving the evolution towards interoperability in healthcare.

Second, as the Roadmap acknowledges, 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. Again: 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 interoperability 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. This is an incremental but meaningful step toward systemic tier 2 interoperability. ONC should be careful to avoid policy decisions that will impede or halt this progress.

Perhaps most importantly, tier 2 interoperability should be conceived as a step toward the goal of realizing the full potential of health IT to revolutionize care delivery and reduce costs, not as the ultimate and final goal of federal health IT policy. We are concerned that the Roadmap as drafted aspires to mediocrity.

Tier 3—the open platform. In a very real sense the third tier transcends interoperability by enabling seamless data availability rather than mere exchange capability. This in our view should be the open-ended goal of federal interoperability policy. Virtually non-existent in healthcare today, this type of information exchange is prevalent in other economic sectors where open 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 interoperability 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. If it is to have any significant long term impact the Roadmap *must* acknowledge goals beyond tier 2 interoperability and enable this continuous innovation in health IT—innovation that has been effectively stalled by the perverse incentives created by current health IT policy.

To that end, we offer the following further comments on three critical aspects of interoperability: (1) APIs; (2) Patient-centered exchange; and (3) Governance.

1. APIs

Because APIs are generally solutions, not standards, they must be market-driven. The government cannot mandate, and committees cannot develop, APIs. This truth was well articulated by the JASON Report, “A Robust Health Data Infrastructure” (April 2014): “Standards usually are established through a formal process and are endorsed by a standards organization, such as the IEEE, ISO, or ANSI. There are hundreds of such organizations, most of which are

centered on a particular industry. In contrast, an API is seldom a standard and is usually dictated by a vendor, although there are some APIs that are highly standardized.”

APIs are widely used in services powered by the consumer internet, and the history of their evolution in that space provides a good preview for how we can expect solutions like APIs to evolve vis-à-vis standards in healthcare. In the 1990s, a “thousand flowers” of internet-based information exchange standards bloomed, ultimately resulting in the selection of HTML, SMTP, RSS, and other use case specific standards. Emerging solutions—browsers such as Mozilla and Internet Explorer, or search engines such as AltaVista and Google—helped solidify the selection of these standards, which in turn spurred the creation of endless new solutions.

Healthcare is in a similar state today. A handful of leading standards for information exchange are beginning to emerge, in part because of the emergence of early solutions like eHealthExchange, the CommonWell Health Alliance, and a host of patient- and provider-focused apps.

Open platform APIs became industry-standard in the consumer internet only when the private sector realized that consumer tolerance for closed systems was waning and openness was a competitive advantage. The development of APIs into standards-based solutions unleashed a new wave of innovation around information exchange.

This evolution toward openness in healthcare cannot be mandated by government.. While we respect ONC’s intention to improve technical standards for sharing and using clinical data, we request that the agency recognize that the industry is in the middle of the evolution described above and, above all else, resolve to avoid impeding that ongoing process. Provider and patient tolerance for closed health IT systems is waning. Solutions like CommonWell signal recognition that openness will be a competitive advantage in healthcare. If federal policymakers want to encourage the evolution that is already underway, they should not subsidize the use of health IT that does not openly exchange information and should not continue to prop up business models that are predicated on treating patient information as a proprietary asset to be silo-ed.

2. Patient-Centered Exchange

Any government action taken toward achieving interoperation in healthcare should be animated by the ultimate goal of achieving patient-centered exchange. Too often today 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 a corporate actor that is inaccessible, unaccountable, and often unknown to the patient.

Patient-centered exchange appropriately gives patients control and authority over their health data, enabling them to access their data directly or authorize access to their data by third parties. It also ensures that authorized healthcare providers can access patients’ longitudinal health information from any health IT platform, without technical, administrative, or financial restrictions.

Again, the health IT industry is already moving toward achievement of this goal without government involvement. CommonWell provides a patient-matching and record location service that is fundamentally patient-centered. All information exchange is based on informed

patient consent. Once that is obtained, any authorized provider can access patient information, regardless of health IT platform, enabling better care coordination and informed decision making. This sort of patient-authorized, unrestricted information flow will in due time become expected industry standard, with multiple solutions like CommonWell in the market.

3. Governance

We do not agree with ONC's assessment that a national set of "rules of the road" is needed for entities that exchange and use information. Again, the existence of CommonWell and other similar initiatives definitively belies that assertion. As the Roadmap recalls, the industry response to ONC's 2012 request for information on its proposed "Nationwide Health Information Network: Conditions for Trusted Exchange" reflected an almost unanimous desire for ONC to refrain from formal governance activity to allow emerging industry efforts to take shape. The fact that those efforts have taken shape, as outlined above, does not mean that it is now time for ONC to enact formal governance. To the contrary, it underscores the need for continued ONC forbearance. No single government-led process or mechanism is needed to bring together industry efforts. Any such action is likely to impede existing information exchange efforts, not enable them.

We cautioned ONC against creating a federal governance structure in our response to its 2012 request for information, and we reiterate that caution here. National governance is needed even less now than it was in 2012. Industry solutions are evolving rapidly. What was then theoretical is now occurring. Many data sharing networks exist and are able to establish their own inter-organization governance without government intervention.

athenahealth appreciates ONC's efforts to make interoperability a central piece of its policymaking. Nothing above should be read to impugn either the efforts or the motivations of the hard-working and thoughtful officials who labored to generate the Roadmap. The abysmal historical performance record of the health IT industry is to blame for the understandable impulse to ever more intrusive government intervention in the health IT marketplace, the efficient functioning of which is crucial to all varieties of health reform. However, we urge ONC to recognize the significant recent progress made by the industry in response to increasing market demand for 21st century information technology functionality in healthcare, and to take an approach that is far more restrained and outcomes-focused than that which is contemplated by the Roadmap.

Market-driven interoperation is happening. As we have done before, we urge ONC to adopt a regulatory variant of the Hippocratic Oath: *first, do no harm*.

Thank you again for the opportunity to share our point of view.

Sincerely,



Dan Haley
Vice President
Government and Regulatory Affairs