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Via Email

Re: ACT Comments on Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap (Draft Version 1.0)

Dear Dr. DeSalvo,

Thank you for the opportunity to provide input on the draft Nationwide Interoperability Roadmap (ONC Roadmap). ACT | The App Association is an international grassroots advocacy and education organization representing more than 5,000 small and mid-size app makers and information technology firms. It is the only organization focused on the needs of small business innovators from around the world. ACT advocates for an environment that inspires and rewards innovation while providing resources to help its members leverage their intellectual assets to raise capital, create jobs, and continue innovating.

The app economy has emerged to become a $68 billion industry in just six years and the mobile health sector is growing even faster. Current revenues in the mobile health economy top $4 billion and are expected to reach $26 billion by 2017.[1] Over three-fourths of the top health apps are made by small companies located all over the country. Our members are the software developers building the health apps, software, and IT systems of tomorrow. And interoperability is key to making those apps work.

ACT appreciates the ONC Roadmap's recognition that interoperability must go beyond semantics to true data exchange. ONC's definition of interoperability discusses the "ability of the system to exchange" data "without special effort on the part of the user."[2] While the app maker builds their user experience (UX) and user interface (UI) to best meet the needs of their users, the underlying data must be in a standard form that can be incorporated into an app.

The average daily use of health apps has grown at twice the rate of app usage overall and consumers are increasingly turning to apps to track their health data and communicate with their healthcare providers. Interoperability is necessary to allow patients to use the data they generate and share it with their care providers. This, in turn, can lead to better patient engagement and outcomes.

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[1] Mobile Health Economy Study, ACT | The App Association (last visited April 1, 2015) *available at* http://actonline.org/mobile-health-report-2014/.
[2] ONC Roadmap, pg. 18.

Finally, we appreciate that the ONC recognizes that the opportunities for entrepreneurial third party app makers depend on the flow of EMRs across both institutional and mobile-based technologies.[3] Mobile apps have already changed the way that patients engage in their healthcare, but increased growth depends on the interoperability of health data both to and from these mobile apps.

While recognizing the effort ONC has put into this document, we see four key areas that continue to need work:

1. Timeframe: 10 years is too long
2. Datasets: 25 is too few
3. Incentives: unless there is economic benefit to improvement, interoperability will languish
4. Existing structural and informational barriers

Embrace the Speed of Innovation

The speed of technological innovation is exponential and 10 years is too long to wait for interoperability. The ONC Roadmap provides a good start but app makers are focused on building their apps in the next 10 months, not 10 years. ACT urges ONC to focus their efforts on interoperability over the next three years.

Think of the innovation in health technology in the last 10 years: the advent of remote monitoring tools, wearable medical devices, and the exponential growth of telemedicine. The next 10 years will be equally as innovative but that innovation will require interoperability, to allow patients to interact with their EMR and to add their PGHD to their EMR.

A focus on the short term (three years) will more clearly concentrate efforts around making inoperability a reality in a reasonable time frame. While there will always be more that can be done, the bulk of the efforts around interoperability need to be concentrated over the next three years.

Interoperability Goals Must Be a Step Forward

The ONC Roadmap picks out only a few core data sets on which they focus their efforts around interoperability in EMRs. While the limitation of data sets is designed to give interoperability a focus, it feels like a step back. App makers currently use hundreds of data sets in building their apps. These varied data sets are what make apps valuable to patients, care teams, and healthcare providers. The ONC Roadmap is designed to push the process forward and limiting the data which is part of interoperability does not do that.

The availability of more data sets means that app makers can build apps which take advantage of that available data to the benefit of patients and providers. If that data is already out there, why keep it out of the interoperability process? The goal of interoperability is to create a way for EMRs to be portable and useable by the patient and their healthcare team. If the interoperability effort is limited, it will slow innovation.

Economic Incentives Critical for Interoperability

In order for ONC to motivate all parties, there must be clear economic incentives to promote interoperability. While the benefits of interoperability are tremendous, there are costs associated with its adoption and implementation.

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[3] ONC Roadmap, pg. 10.

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The ONC Roadmap talks about alignment of incentives but there are no clear economic incentives to make the interoperability process desirable for all parties. If there are no economic incentives (or economic punishment), businesses will not spend their time and resources making interoperability a reality.

Implementing interoperability will incur costs to businesses in the healthcare space. There must be an incentive to implement, otherwise hospitals and health insurance companies are not going to pay to build a new interoperable way to access their data and app makers are not going to take the time to build new health apps.

ACT encourages the ONC to work with industry and the Centers for Medicare and Medicaid Services (CMS) to find areas where economic incentives can be applied. Health apps are an important tool for patients and doctors and we urge this cooperation to be expanded to best meet the goals of the ONC Roadmap.

Existing Structural Problems that Hamper Interoperability

A key structural problem for interoperability comes from unclear health data laws and regulations, specifically the Health Insurance Portability and Accountability Act (HIPAA). As the ONC acknowledges, "many organizations have misinterpreted HIPAA rules and other regulations"[4] to mean that data should not be easily accessible, even by the patient themselves. If this ONC Roadmap is to succeed, it needs to include concrete deadlines for clear guidance on health data and technology from HHS and other agencies.

Information on health data requirements is still mired in a Washington, DC, mindset that revolves around reading the *Federal Register*, or hiring expert consultants to "explain" what should be clear in the regulation itself. Not surprisingly, app makers do not find the *Federal Register* to be an effective resource when developing health apps. While the ONC has taken steps to provide developer-friendly information, there are still limited resources available for app makers, especially around HIPAA.

In this uncertain environment, app makers often find their innovative products dismissed or their UX/UI compromised simply because the customer, a care team, or healthcare provider, is unsure of their risks and obligations under existing law. App makers and health care organizations are stymied by the absence of information on the patchwork of regulations around health data.[5] App makers need clear guidance on how HIPAA and other laws support, and even require interoperability, of health data.

Priority Use Cases to Inform Policies

The three uses case which would best inform priorities for the ONC are:

20. Patients, families and caregivers are able to use their personal devices such as smartphones, home BP cuffs, glucometers and scales to routinely contribute data to their longitudinal health records and use it or make it available to providers to support decision-making.

36. Individuals integrate data from their health records into apps and tools that enable them to better set and meet their own health goals

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[4] ONC Roadmap, 14.

[5] Clarity in guidance will also assist patients in understanding their right to access their EMR, which the ONC has pointed out is key to moving interoperability forward.

52. At-risk patients engage in healthcare monitoring programs which can detect life threatening situations (such as patient down and unresponsive) using at-home monitoring devices and electronic communications such as eVisits and telemedicine

These cases focus on the key goal of interoperability: allowing patients access to their health data through standardization around how health data is exchanged. These cases should be considered in terms of all the building blocks outlined in the Roadmap, including: privacy and security; supportive business, clinical, cultural, and regulatory environments; rules of engagement; and governance.

Thank you for the opportunity to comment and ACT looks forward to working with the ONC on interoperability.

Sincerely,

Morgan Reed
Executive Director