



April 2, 2015

Dr. Karen DeSalvo  
National Coordinator for Health IT  
Acting Assistant Secretary for Health  
U.S. Department of Health and Human Services  
200 Independence Ave SW  
Washington, DC 20201

**Re: Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap;  
Draft Version 1.0**

Dear Dr. Salvo:

Thank you for the opportunity to provide feedback on the draft version of *Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap*. As you know, we believe that widespread health information exchange and interoperability is vital to achieving better care, smarter spending, and healthier people.

Over the last fifteen years, Humetrix has developed numerous mobile health applications that enable consumers to engage with the world around them in new and innovative ways using their own health care data. One of these applications – iBlueButton – incorporates existing EHR standards critical to interoperability including secure Direct messaging for data transport and the HL7 C-CDA format for the content of records (as defined in the Blue Button+ standards). iBlueButton enables patients to easily and securely receive, view, aggregate on their mobile devices clinic and hospital discharge summary records from *most* 2014 certified EHRs, for them to communicate an up to date medical history at each point of care. iBlueButton has won multiple industry innovation awards, including two ONC Industry Innovation awards, and is widely viewed as one of the most usable and novel mobile personal health record (“PHR”) applications on the market today. Humetrix is also offering other patient and provider facing mobile applications, including SOS QR and Tensio, which with iBlueButton facilitate patient-provider communication and deliver scalable consumer-mediated exchange solutions that can materially advance interoperability with the current health IT infrastructure and advances provided by mobile technology.

### **Our Comments on the Draft Roadmap**

Given this perspective, our comments below are focused on the important role that consumers and caregivers play in facilitating interoperability, as well as the existing standards and tools that can be used to achieve near-term interoperability. While we believe that the draft roadmap is an important first step toward outlining a set of milestones that could be used to achieve interoperability, greater specificity is needed to clarify exactly what role and actions are needed by stakeholders to achieve interoperable patient-centered care. We have suggested several concrete action items below, as well as a commitment Humetrix will make to do its part in advancing our collective efforts.

## I. Building on Existing Health IT Infrastructure

On pages 9-10 of the draft roadmap, the Office of the National Coordinator for Health IT (“ONC”) outlines a number of “guiding principles” that are used to identify functional and business requirements for interoperability, and to develop “foundational” short and long-term critical actions. One of these principles is to “build upon existing health IT infrastructure.”

We recommend that ONC be more specific about how it will build upon existing health IT infrastructure, including existing meaningful use standards and technologies, in each of the building block areas discussed in the draft roadmap. Action is needed to ensure that providers and electronic health record (“EHR”) are appropriately operationalizing the existing infrastructure of policies, standards, and technology to support ubiquitous, bidirectional patient-provider communication. Simple solutions should be implemented at scale first, using existing infrastructure.

**Critical Action #1:** The Centers for Medicare & Medicaid Services (“CMS”) should leverage its position as a major payer of health care to require eligible providers and hospitals to “turn on” and be accountable for using required functionalities in certified electronic health records, including the Direct transport protocol (“Direct” or “Direct messaging”) not only for provider to provider exchange but more importantly for provider to patient communication using apps chosen by the patient which conform to the Blue Button+ standards established by the ONC S&I framework.

**Critical Action #2:** EHR and HISP vendors should provision their systems with Trust Anchors for patient facing applications to enable Direct messaging, including those administered by National Association for Trusted Exchange (“NATE”), in their certified EHR products to allow for provider-patient communication using and Blue Button+ conforming apps. If EHR vendors are unwilling to do so, ONC should require inclusion of Trust Anchors for patient facing applications through Meaningful Use regulations as we and a number of other application developers and consumer facing organizations called on the ONC to do in our letter to you of September 12<sup>th</sup> 2014.

## II. Improving the Certification Process to Ensure Production Products Meet Requirements

We agree that “[a] diverse and complimentary set of certification and testing programs will need to be in place to achieve a nationwide learning health system.” For example, we have found that while some EHR systems may have successfully been certified using a single or small number of test C-CDAs as required under current testing procedures, they are not able to generate well-coded C-CDAs which meet the HL7 C-CDA standard when deployed in a health care setting. As indicated in the draft roadmap, continuous real world testing *should* be used as a “check” to ensure that certified EHR products continue to function as intended under the requirements set out by ONC and CMS.

**Critical Action #3:** ONC and the National Institute of Standards and Technology (“NIST”) should develop testing protocols that ensure that EHRs continue to meet meaningful use requirements when in production. Specifically, ONC and NIST should ensure that C-CDA files conform to standards when deployed in a health care setting at scale.

### III. Using Existing Mobile Technologies to Mitigate Effects of “Portal Fatigue”

Echoing comments made by the Consumer Workgroup of the Health IT Policy Committee on the Federal Health IT Strategic Plan, we believe that making consumer-facing health IT more user-friendly for consumers and more functional for consumers and providers is part of creating truly patient-centered care. A critical part of this is recognizing and enabling currently available mobile technologies, as these have the power to engage patients that are otherwise not engaged in the system, and make health and health care more convenient for patients and their caregivers while still meeting the requirements of the meaningful use program.

In contrast, patient portals have not been an effective way to encourage patient engagement and true interoperability. Many portals suffer from usability issues, and logging into a portal is not a convenient user experience when it comes to coordinating information sharing at the point of care. Further, patients who see multiple providers are required to log into multiple portals and are not able to easily aggregate information across portals into one consolidated record. In addition, consumers are generating health care data outside their care team that their providers need to deliver safe, high quality care and urgent care clinics, retail clinics are likely to further increase health data fragmentation. Patients and family caregivers need the ability to aggregate health records in one place and share relevant data seamlessly and efficiently at every point of care.

The limitations of patient portals, particularly for vulnerable populations, were highlighted in a study recently published in the American Journal of Managed Care, which found that non-white patients and patients who spoke Spanish as a primary language tended to access their personal health records through patient portals less frequently than white, English-speaking patients. There is, however, data that shows that these populations heavily use mobile phones to access the Internet given their relative low cost and general affordability. For example, the most recent data from PEW Research Center shows that 70 and 71 percent of Black and Hispanic adults own a smartphone, compared to a national number of 64 percent across ethnicities and races.

Given the above, we believe that portal fatigue will likely detract from consumers’ ability to drive interoperability. As a result of the above, mobile technologies should be viewed as a near-term solution to the challenges associated with traditional patient portals, as new technologies such as Humetrix’s iBlueButton, are enable providers to use Direct messaging to transmit a patient’s health record to their patients’ mobile phones at the point of care, enabling patients to immediately view their record on their mobile phones and share this record with another provider at any subsequent point of care. Aggregation can take place immediately without multiple steps of logging into multiple portals. This can be accomplished today using Direct technology to meet the view/download/transmit meaningful use requirements. We do not have to wait for APIs for patients to be able to realize the benefits and convenience of this technology and existing standards.

**Critical Action #4:** ONC should track rates of smartphone adoption/use and adopt policies that enable all consumers and vulnerable populations to effectively use their health information as needed on their mobile devices.

**Critical Action #5:** ONC should focus on ways that it, other federal agencies, and other stakeholders can immediately increase individuals’ access to their health information via mobile devices, as well as their ability to contribute, share and manage their health information on a mobile device.

#### **IV. Patient and Provider Communication as a Critical Tool**

As currently written, the roadmap directs “a majority of individuals and their caregivers...[to] demand access to their electronic health information in a format they can use to manage their health or that of others.” An important first step in creating this demand is ensuring that patients and/or their caregivers *know* that their information is available. For the most part, our experience has shown that the general public is not currently aware of either their rights under HIPAA to electronically access their health information or of the ability of providers to send this information to them using Direct messaging or of the currently available apps for them to receive, use and share information with other providers. It is thus incumbent upon trusted sources of health care information, including payers (like Medicare) and providers, to make sure that patients know where their information is stored, how they can access it, and tools that are available to help them understand and use it. We believe that a communications campaign is needed to do this basic education, which may result in a groundswell of demand as envisioned in the draft roadmap.

**Critical Action #6:** The Department of Health and Human Services (“HHS”) should educate providers, patients and their caregivers regarding tools that give them the means to receive, use and share their health records, including Blue Button+ compliant mobile and other patient facing applications.

**Critical Action #7:** The Office of Civil Rights (“OCR”) should issue guidance clarifying that individuals have a right to receive their designated record set information in a personal health record through Direct when a health care provider has certified EHR technology or other technology that readily supports such access. Humetrix and other application developers along with a number of patient facing organizations sent a letter to the OCR requesting this action on January 30, 2015.

**Critical Action #8:** CMS should publish an FAQ on its website clarifying that consumer facing applications which conform with Blue Button+ standards can be used to meet the view/download/transmit Stage 2 meaningful use requirement.

#### **V. Encouraging Interoperability in Health Care Programs Other Than Traditional Medicare**

As is reiterated throughout the draft roadmap, interoperability is a challenge that is shared across health care programs and stakeholders. As a result, we agree that we must look beyond the Medicare program when considering how best to drive widespread interoperability across the nation. We encourage HHS to consider the levers it might have available to encourage other payers to require the use of health IT and support interoperability.

**Critical Action #9:** CMS should use available levers to encourage increased interoperability through programs other than traditional Medicare, including the Exchanges, Medicaid, Medicare Advantage, and other state initiatives.

**Critical Action #10:** CMS should require states receiving federal funds for the provision of health care (either through a CMS demonstration program or for Medicaid) to have an interoperability plan, which should include implementation of patient access to their longitudinal health record using mobile and other applications conforming to the Blue Button+ standards

**Critical Action #11:** CMS could also require that Medicare Advantage plans and commercial plans offered through the Exchanges incorporate requirements facilitating patient engagement through mobile tools conforming to Blue Button+ standards that allow patients to access their health records.

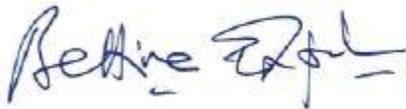
### **Our Commitment to Achieving Interoperability**

To support the collective effort to achieve nationwide interoperability, Humetrix will maintain and support mobile technologies that allow patients to view, aggregate and use their health care data through, for example, sharing it with health care providers. We will continue to receive, display and parse C-CDAs in support of meaningful use requirements, and will turn on the “send” function of our two-way Direct messaging service so that patients using our products can send and receive data (including patient generated data) with provider EHR systems.

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Thank you again for the opportunity to provide comments on the draft interoperability roadmap. We look forward to staying engaged with ONC on this critical issue. Please do not hesitate to reach out to me if I can be a resource on this or any other issue.

Sincerely,

A handwritten signature in blue ink that reads "Bettina Experton". The signature is fluid and cursive, with a horizontal line at the end.

Bettina Experton, MD, MPH  
President & CEO  
HUMETRIX  
1155 Camino del Mar, #503  
Del Mar, CA 92014, USA  
Tel: (858) 259-8987, Ext. 210  
Cell: (619) 980-5888