



Written Statement of
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Identifying barriers and enablers for device interoperability
Health IT Standards Committee
Clinical Operations Workgroup

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Good Morning Chairman Ferguson and Members of the HIT Standards Committee, Clinical Operations Workgroup. My name is Robert Jarrin, Co-Chair of the Continua Health Alliance US Policy Working Group and Senior Director of Government Affairs for Qualcomm Incorporated. The Continua Health Alliance is a non-profit, open industry coalition of healthcare and technology companies, patient organizations and associations that are joined to collaborate and improve the quality of personal healthcare. On behalf of the 240 members of Continua, I would like to thank you for the opportunity to present testimony on the important issue of medical device interoperability.

Continua is not a standards setting body – rather the Alliance selects existing commercially available standards, works within them by adding definitions or refinements and finally tests and certifies interoperability of devices among member companies. The Alliance then drafts guidelines on how to use those existing standards to achieve true interoperability across many companies and many devices.

By extending interoperable personal health solutions into the home, Continua hopes to foster independence, empower individuals and provide the opportunity for personalized health and wellness management. Continua members strive to improve health outcomes through the electronic exchange of information — whether data, images and video — to aid in the practice of medicine and advanced analytics. By encompassing a myriad of technologies that include remote patient monitoring over fixed and mobile networks, Continua embraced the descriptive term “e-Care” as defined by the Federal Communications Commission as described in the National Broadband Plan.

The foundational elements of e-Care are rooted in health information technology. Continua strongly believes that health information technologies are not limited to the mere exchange of electronic health records among providers, but rather encompass a



broader ecosystem that begins with how data is captured and derived electronically from a patient through interoperable remote patient monitoring devices, sensors, applications and products. That data is then transmitted through common specifications to populate the patient’s EHR. Those rich elements of information are then further utilized throughout the continuum of care that will be further enhanced by a nation-wide health information network (NWHIN).

I. Question: Please comment on your needs and issues related to the use of health devices in managing health and wellness, in home care and remote health monitoring.

Continua remains committed to the original goals established by the Office of the National Coordinator (ONC) to enable significant and measurable improvements in population health through a transformed healthcare delivery system. It is a vision in which: all patients can be fully engaged in their healthcare through stored or real-time access to their secure medical information; patients are linked to medical professionals; caregivers and family members (as they desire); individuals benefit from early detection, prevention, and management of chronic diseases; better care coordination can effectively reduce, redundant and costly testing; medical errors can be avoided as individuals can rely on proactive information systems that improve the delivery of healthcare.

Each stage of meaningful use serves as the foundation for the next. From the onset of the meaningful use process Continua has maintained that in order to truly achieve the goals described by the ONC, and implemented by the HIT Policy and Standards Committees, that meaningful use objectives need to be expanded to place a greater emphasis on how patient data is captured, derived and transmitted. How a patient’s data is captured and derived is as critical and vital as the EHR which that data ultimately helps form. ONC must remain consistent with its definition of meaningful use and promote, not only the systems that govern EHRs, but also the adoption and use of interoperable HIT technologies that will populate the information that becomes the EHR. By focusing primarily on EHRs and quality measures, while not giving enough weight to how EHR data is gathered, limits the health care system’s ability to fully benefit from implementing EHR technology.

II. Question: How should integration of home and remote monitoring with EHRs be addressed?

Continua commends the Health Information Technology Policy Committee (HITPC) for developing preliminary recommendations concerning Stage 2 objectives for “meaningful use” of electronic health records (EHRs), for the purposes of the Medicare



and Medicaid EHR incentive programs. The HITPC’s proposed meaningful use objectives and measures for Stage 2 and possible Stage 3 criteria offer a comprehensive approach by including elements to engage patients and families in their care, improving care coordination, improving population health, and ensuring adequate privacy and security protections. These elements build upon the original goals to improve quality, safety, efficiency and reduce health disparities.

Continua is encouraged, by several elements included within the proposed matrix for meaningful use objectives and measures for Stages 2 and 3. As stated in the request for comments, the HITPC is “...seeking comment on what steps will be needed in Stage 2 to achieve ... proposed Stage 3 objectives Specifically, under “Engage Patients and Families in Their Care” the HITPC states it is “seeking comment on what steps will be needed in Stage 2 to achieve this proposed Stage 3 objective.”

Two specific elements are:

1. “Offer electronic self-management tools to patients with high priority health conditions”
2. “Offer capability to upload and incorporate patient-generated data (e.g., electronically collected patient survey data, biometric home monitoring data, patient suggestions of corrections to errors in the record) into EHRs and clinician workflow”

If the HITPC’s goal for Stage 2 is to remain consistent with the Final Rule, it must include rigorous expectations for health information exchange. Specifically, Stage 2 must include requirements for incorporating structured results with the expectation that providers will electronically support transitions in care across separate care settings and throughout several EHR systems. Specifically, Stage 2 should include applying the criteria more broadly to all outpatient hospital settings (not just the emergency department).

Stage 2 is supposed to build upon Stage 1 by adding new functionalities whose provisions were necessary to maximize the potential of EHR technology. Remote patient monitoring fits into the overarching policy structure of meaningful use. Continua urges ONC to ensure the use of these technologies because they are integral to the achievement of these national goals and priorities. Commercially available technologies can be used by patients, eligible providers (EP) and other professionals to achieve the goal of data capture that CMS established in Stage 1 of the meaningful use rule.

Therefore, ONC should accelerate the steps to ensure EPs offer electronic self-management tools to patients with high priority health conditions as well as offering the capability to upload and incorporate patient-generated data (e.g., electronically collected patient survey

data, biometric home monitoring data, patient suggestions of corrections to errors in the record) into EHRs and clinician workflow as Stage 2 criteria and not Stage 3.

Those steps should:

- establish a percentage based quantity like other current proposed Stage 2 criteria that are assigned a numeric value representing the number of patients that must be utilizing the particular ability or service; and
- promote those technologies that can tie into or help accomplish other Stage 2 criteria that are currently under consideration; and
- include proposed criteria such as 80 percent of patients that should be offered the ability to view and download via web-based portal relevant information contained in their records, or 20 percent of patients to use a web-based portal at least once to access their information on encounters or for longitudinal records.
- develop templates that will streamline presentation of the remotely captured data to offer clinicians data that will be valuable and quickly integrated into the care plan.

The HITPC should seek to encourage utilizing electronic self-management tools that are interoperable, commercially available, home-based medical devices, sensors, applications and products that communicate via wired, wireless or mobile interfaces. Services provided through remote patient monitoring (RPM) devices extend an EP’s reach and should be viewed as an augmentation of their services. For instance, RPM devices can be used to “record and chart changes in vital signs.”

RPM devices can directly populate a patient’s EHR whether the device is used in the professional’s office or in the patient’s home or anywhere else. These technologies collapse time, space and distance to more effectively monitor patients, develop analytical trends, and ultimately save lives while maximizing efficiency and avoiding those health crises that incur lengthy hospital stays and costly readmissions. Increasingly, devices are utilizing broadband technologies over wired, wireless and mobile networks to seamlessly provide important patient information to healthcare professionals, clinicians and their families at lower costs and in secure, stored or real-time usable formats.

Ultimately, RPM devices can aid EPs in meeting CMS’ objectives for all three stages of meaningful use. Because RPM can be used for all three stages, it is logical to include the foundation for its use in Stage 2. Continua urges the inclusion of this step in Stage 2.

III. What is your experience with healthcare devices and device interoperability?

As mentioned above, Continua uses the term eCare to refer to the class of health information technologies that can facilitate any kind of virtual visit or electronic connectivity outside of traditional office visits among patients, family members, and



medical professionals. eCare includes personal connected health as well as telehealth. It can be secure text messaging between a senior patient and their doctor to change a medication dosage, an audio chat, or a video web cam visit. It can be personal connected health with an in-home or mobile broadband device that can help providers track and trend data like blood pressure and weight fluctuations that seniors and other patients can take by themselves on a regular basis. eCare may also include using connectivity to help patients remember to take a medication, capture a vital sign, or view customized content sent to them by their clinician to teach them about managing their own disease. eCare expands and extends the efforts of medical professionals by providing information to and from patients without geographic obstacles.

To realize the quality improvement and cost-containment goals of our nation, we must harness the benefits of technologies that allow patients and care providers to use real-world, remotely-collected data to make decisions about their health on a continual basis, rather than waiting until a condition has set in that requires them to schedule an urgent office visit or go to the emergency room. By tracking vital signs and other health data on a more regular basis and sharing it through secure systems, eCare offers many beneficial clinical capabilities:

- Empowers patients with tools that help them make sense of —and help manage— their own care;
- Collects real-world biological and behavioral data and trends on a regular basis with alerts for out-of-norm situations;
- Facilitates virtual visits with providers, whenever and wherever appropriate, via a range of electronic media;
- Enables social networking, awareness, and care support from family and friends who are nearby or distant;
- Personalizes care plans and educational content for each individual based on their needs, preferences, data, and capabilities; and
- Triage precious medical resources to enable the right amount of care to occur in the right place and time.

While there are many challenges associated with the successful design, implementation and deployment of personal telehealth systems, one of the more obvious problems in

early telehealth solutions has been the lack of device interoperability which requires broad industry support behind particular standards.

Integrator / Purchaser

Integrators (companies producing eCare solutions made up of components from a number of different vendors) and purchasers (healthcare providers that will be purchasing these solutions and offering them to their patients or members) both require a wide variety of system vendors and components to select from.

Interoperability is important as it allows integrators and purchasers to select from a wide variety of personal health devices offered by multiple vendors.

Product Designer

From the perspective of a product designer, device interoperability is essential. If the objective of the product designer is to design equipment that will communicate with a wide range of telehealth peripherals (for example, weight scales, blood pressure monitors, glucose meters), it is very likely that the desired set of peripherals be developed by multiple vendors. Interoperable solutions will minimize cost, improve design and development efficiencies and enable separation of concerns that device vendors can focus on devices, software vendors can focus on software development, and service providers can focus on service delivery by utilizing well-defined, unambiguous commercial standards and guidelines.

IV. What standards or standards related capabilities are most relevant and important to the meaningful use of EHR technology?

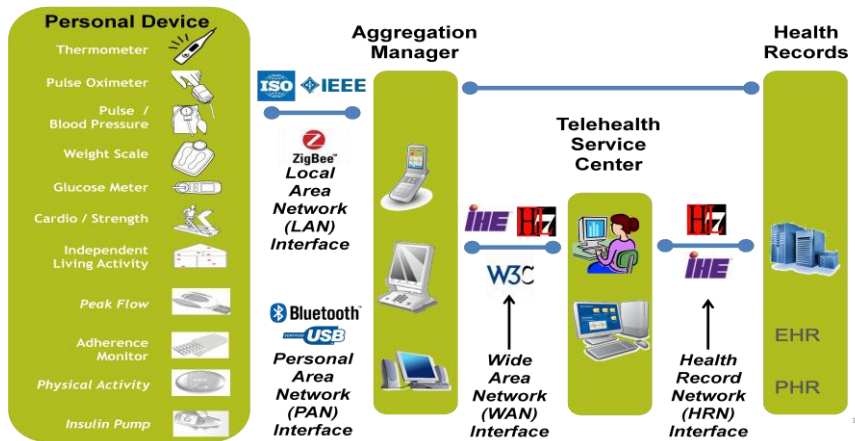
Approach

Continua Health Alliance was founded in 2006. The Alliance leveraged examples from other solution domains such as home networking (for example, Wi-Fi Alliance and Digital Living Network Alliance) in order to help define its overall approach. The result was the following methodology:

- Select existing, applicable industry standards
- Extend these selected standards where required (to meet user needs identified in use cases and requirements)
- Eliminate ambiguity in interpretation of these standards through a collection of interoperability guidelines
- Develop a certification process that guarantees products meet the guidelines and provide the consumer a high-quality user experience

Continua put in place a flexible architecture that allows for a common approach but also accommodates regulated and unregulated products from the various application

domains. The figure below shows the various components and the interfaces that constitute an end-to-end solution.



V. If you could wave a magic wand to effect one change to enable more effective and widespread use of health care devices, what would that be? (We've offered four)

Despite the success Continua members have achieved in developing devices and services as assistive technologies for patients with chronic disease and succeeded in making sure that these devices interoperate, significant barriers restrict the integration of eCare into patient care plans. In order to ensure that patients and clinicians have full access for their optimum healthcare, we respectfully submit the following recommendations:

1. Stage 2 Needs to be Consistent with the Previous Meaningful Use Final Rule

The ONC should accelerate its proposed Stage 3 objectives and seek to include “Engage Patients and Families in Their Care” as Stage 2 objectives. Additionally, two specific elements to consider are:

- “Offer electronic self-management tools to patients with high priority health conditions”
- “Offer capability to upload and incorporate patient-generated data (e.g., electronically collected patient survey data, biometric home monitoring data, patient suggestions of corrections to errors in the record) into EHRs and clinician workflow”

If the HITPC’s goal for Stage 2 is to remain consistent with the Meaningful Use Final Rule, it must include rigorous expectations for health information exchange. As the ONC considers the next Stage of Meaningful Use, Stage 2, it must include requirements for incorporating structured results with the expectation that providers will electronically support transitions in care across separate care settings and throughout several EHR systems. Specifically, Stage 2 should include applying the criteria more broadly to all outpatient hospital settings (not just the emergency department).

2. Payment Reform for eCare

As noted in the Federal Communications Commission National Broadband Plan, reimbursement reforms are essential to incentivize the meaningful use and widespread adoption of eCare technologies. Simply stated, reimbursement issues are a barrier to the adoption of health IT. The Centers for Medicare and Medicaid Services (CMS) define telehealth services as the use of medical information exchanged from one site to another via electronic communications to improve a patient's health.¹ Electronic

¹ See Centers for Medicare and Medicaid Services, “Telemedicine and Telehealth,” <http://www.cms.hhs.gov/Telemedicine/>.



communication means the use of interactive telecommunications equipment that includes, at minimum, audio and video equipment permitting two-way, real-time (with limited exceptions) interactive communication between the patient, and the physician or practitioner at the distant site. The definition includes limitations on the types of originating sites of care that can be used, in addition to the requirement that an originating site must be located in either a health professional shortage area (HPSA) or in a county not classified as a metropolitan statistical area (MSA).

eCare reimbursement should be permitted in both rural and urban areas, home and clinical settings and through an inclusive list of clinicians. The limitations on which types of originating institutions and which fields of healthcare are eligible for telehealth reimbursement are outdated. Healthcare management should not be limited to only live encounters, where store-and-forward technologies are perfectly capable of providing reliable, consistent, diagnostic care. Interoperable personal telehealth and remote monitoring of data can be used for disease management, safety, health and wellness. If a Medicare benefit plan covers a service, then that plan should also cover the same service when it is performed via eCare.

3. Establish Blueprints for the use of eCare in states and communities.

We can learn from the successful deployment of 35,000 chronic care patients served by remote patient monitoring through the Department of Veterans Affairs. Although a closed system, the results are for patients with the same illnesses that Americans across the nation face. We need to do the hard work of factoring new payment plans, work flow systems and efficiently using community resources to care for our patients at home. We offer the resources of the Continua Health Alliance to convene the appropriate participants – hospital systems, doctors, technology companies to work with Congress and HHS to design a system that works for all stakeholders.

4. Make home broadband adoption for all Americans a top priority following recommendations in the FCC’s National Broadband Plan.

Extending broadband adoption is especially important in rural parts of the country to enable new independent living and home health care solutions. Similar to the National Broadband Plan, Continua supports the FCC’s notion that a Health Care Broadband Infrastructure Fund should be established to subsidize fixed, wireless and mobile network deployments to augment health care delivery in locations where existing networks are insufficient.

VI. Future Vision of what eCare can deliver

In 2005, the Center for Aging Technologies (CAST), developed *Imagine—the Future of Aging*. Rather than describe what the future could be, I invite you to watch the video which will give you a glimpse, through the eyes of one family, of what the future could look like with help from developing technologies that are possible, practical, affordable and ethical. You will also see how these technologies have the potential to improve care, preserve independence, and ensure quality of life while reducing costs.

We must, however, take action through vision, leadership and national commitment to prepare for the demographic and economic changes that will inevitably transform healthcare.

<http://www.youtube.com/watch?v=SBH9dkCZsXQ>



Addendum:

Successful Case Studies

These current services and future health information technologies will be the key to improving the delivery of clinical services and healthcare quality, as well as containing healthcare costs. Many studies have shown the value of personal connected health. For example, the New England Healthcare Institute (NEHI) “2008 Research Update, Remote Physiological Monitoring” found that remote patient monitoring resulted in a 60 percent reduction in hospital readmissions compared to standard care and a 50 percent reduction in hospital readmissions compared to disease management programs without monitoring. The same study found that remote patient monitoring has the potential to prevent between 460,000 and 627,000 heart failure related hospital readmissions each year. Based on this reduction in readmissions, NEHI estimated annual national cost savings of up to \$6.4 billion dollars.



As our nation looks for ways to improve quality, access, and costs of healthcare, it is important to realize that eCare technologies can save lives and dollars. For example, the Department of Veterans Affairs (VA) examined this issue in its report, “Care Coordination/Home Telehealth: The Systemic Implementation of Health Informatics, Home Telehealth and DM to support the Coordination of Veteran Patients with Chronic Conditions.” The VA found that implementing telehealth to coordinate patient care led to a 25 percent reduction in the number of bed days and a 20 percent reduction in hospital admissions. The report showed a cost of \$1,600 per patient per annum for the telehealth program compared to \$13,121 for traditional primary care and \$77,745 for nursing home care. Not only were patients able to avoid readmission and improve their health status faster through telehealth services, but taxpayers also saved money.

Role of Personal Connected Health, Telehealth and eCare as Clinical Services and as Improving Health Care Quality in the Patient Protection and Affordability Act (ACA)

eCare, including personal connected health and telehealth, complements clinic and hospital visits and improves healthcare quality. By monitoring their own data from home, patients and their caregivers become more engaged in self-care and aware of health trends. eCare can also improve consumers’ access to care, particularly in rural areas, by easing logistical burdens and reducing or eliminating the need to travel to a provider’s office for routine visits. In addition, through the use of personal connected health, providers have more information on a timely basis upon which to make medical decisions that can assist in addressing health problems before they become crises. As eCare removes geographical restrictions, patients will gain access to needed specialists who may not be local.

Recognizing these challenges and opportunities, ACA includes numerous provisions designed to promote personal connected health, telehealth, and other eCare services. For example, the Secretary of HHS is required to develop guidelines for a payment structure that provides increased reimbursement or other incentives for: improving health outcomes through quality reports, case management, care coordination, chronic disease management, medication and care compliance initiatives (including medical home); activities to reduce hospital readmissions; activities to improve patient safety and reduce medical errors through the appropriate use of best clinical practices, evidence-based medicine, and health information technology; and wellness and health promotion activities. eCare is at the crux of all of these services. (ACA § 1311)

Many of the most promising ideas for healthcare delivery innovation depend on eCare services. ACA looks to increase the use of eCare services to provide for future



improvement in healthcare delivery. For example, the Independence at Home Demonstration Project, designed to improve care for chronically ill Medicare beneficiaries, defines an “independence at home medical practice” as one that “uses electronic health information systems, remote monitoring, and mobile diagnostic technology.” (ACA § 3024) Accountable Care Organizations participating in shared savings programs under PPACA are required to “define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care, such as through the use of telehealth, personal connected health, and other such enabling technologies.” (ACA § 3022) Further, the Center for Medicare and Medicaid Innovation created by ACA may test models that support care coordination through “a health information technology-enabled provider network that includes care coordinators, a chronic disease registry, and home telehealth technology,” and may consider whether a model under review “utilizes technology, such as electronic health records and patient-based remote monitoring systems, to coordinate care over time and across settings.” (ACA § 3021) Without inclusion of eCare, from the beginning, as a clinical service or service that improves quality, our healthcare system will not benefit from or encourage the use of personal connected health or telehealth services. We urge policymakers to look to the future of what healthcare delivery can be through the use of wired, wireless, mobile broadband and whatever new forms of technology may appear to allow our uniquely American healthcare system to benefit from eCare as we know it and as we might know it in the future. eCare truly promises to be a disruptive approach that transforms the way that we provide healthcare and becomes an indispensable tool in the future.

Sample of Recently Certified Products

- Nonin 2500 PalmSAT® Pulse Oximeter
- Nonin Onyx® II 9560 Wireless Fingertip Pulse Oximeter
- Roche Accu-Chek® Smart Pix Glucose Device Reader
- A&D Medical UA-767PBT-C Blood Pressure Monitor
- A&D Medical UC-321PBT_C Weigh Scale
- Cypak CPX186 Continua Converter Cable
- OMRON Bluetooth Home Blood Pressure Monitor
- Omron Continua Certified Weighing Scale with a Body Composition Monitor Using Bluetooth Wireless Technology
- Omron Pedometer with Bluetooth Docking Station
- Continua Bluetooth Manager for Windows manufactured by Toshiba
- Texas Instruments MSP430 USB Agent Platform
- Panasonic TOUGHBOOK H1 with Blood Pressure Monitor, Cardiovascular and Weighing Scale device specializations by Bluetooth



- Wipro Continua x73 Manager USB Reference System
- Freescale i.MX Linux AHD Reference Platform running LNI HealthLink/OXP-Libraries and Continua certified as a Manager supporting the Blood Pressure Cuff device specialization
- HealthLink USB Manager with Weighing Scale (OXP lib, PAN client C++ library), winusb Shim
- eHealth Bluetooth(r) Gateway
- Elbrys Networks' Secure Personal Sensor SDK
- Texas Instruments AM/DM37x Linux Reference Platform
- FORA D40 Blood Glucose and Blood Pressure Monitor with Bluetooth Technology
- NTT DOCOMO Mobile Phone with Fujitsu HDP Manager Platform
- Panasonic CF-J10 Compact mobile PC