



Continua
HEALTH ALLIANCE

Department of Health and Human Services
Office of the National Coordinator for
Health Information Technology
Switzer Building
330 C Street, SW
Suite 1200
Washington, DC 20201
Attention: Joshua Seidman

February 25, 2011

RE: Meaningful Use Workgroup Request for Comments - Meaningful Use Stage 2

Dear Mr. Seidman:

The Continua Health Alliance (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 a non-profit, open industry coalition of healthcare, technology and medical device companies working together to improve the quality of health through the use of telehealth, personal connected health, mobile health (mHealth) and independent living technologies for what has been termed “e-Care” by the Federal Communications Commission.¹ Continua is dedicated to establishing interoperable personal health solutions with the knowledge that extending those solutions into the home fosters independence, empowers individuals, and provides the opportunity for improved health and wellness. More information about Continua and its nearly 240 member companies can be found at www.continuaalliance.org.

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;

¹ See FCC National Broadband Plan: Connecting America, rel. Mar. 16, 2010, at 200. See U.S. Senate Special Committee on Aging, Committee Hearing on April 22, 2010 “Aging in Place: The National Broadband Plan and Bringing Health Care Technology Home” http://aging.senate.gov/hearing_detail.cfm?id=324102&.

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; and medical errors can be avoided as individuals can rely on proactive information systems that improve the delivery of healthcare.

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

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 HITPC, the meaningful use objectives need to be expanded to place a greater emphasis on how patient data is captured, derived and transmitted. The foundational elements of health information technology are not limited to the mere exchange of electronic health records among providers, but rather is a broader ecosystem that begins with data captured electronically from a patient, derived through interoperable remote patient monitoring devices, sensors, applications and products. That data is then transmitted through common specifications to populate the patient's EHR. That data is then further utilized throughout the continuum of care made possible by a nationwide health information network (NWHIN).

How a patient's data is captured and derived is as critical and vital as the EHR that data ultimately helps form. For this reason, Continua was gratified and encouraged when the final rule on Meaningful Use Stage 1 recognized that those devices that help populate EHR with data from the patient, if certified, could serve as "EHR Modules" which eligible professionals may adopt to help qualify for an incentive payment. For HITPC to not build upon this in Stage 2, creates an uneven emphasis within the overall meaningful use policy.

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.

Important Elements for Stage 2

Continua is encouraged, however, by several elements included within the proposed matrix for meaningful use objectives and measures for Stage 2 and Stage 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 objective." (The matrix includes possible Stage 3 objectives, but those objectives are only included in the matrix in order

to provide context for the Stage 2 recommendations.)² 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:

- “Offer electronic self-management tools to patients with high priority health conditions”³
- “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”⁴

These elements do build upon the Final Rule, issued by CMS concerning Stage 1, which stated:

The Stage 1 meaningful use criteria, consistent with other provisions of Medicare and Medicaid law, focuses on electronically capturing health information in a structured format; using that information to track key clinical conditions and communicating that information for care coordination purposes (whether that information is structured or unstructured, but in structured format whenever feasible); implementing clinical decision support tools to facilitate disease and medication management; using EHRs to engage patients and families and reporting clinical quality measures and public health information.

We encourage all EPs, eligible hospitals and CAHs to be CMS-0033-F 35 proactive in implementing all of the functionalities of Stage 1 in order to prepare for later stages of meaningful use, particularly functionalities that improve patient care, the efficiency of the health care system and public and population health. The specific criteria for Stage 1 of meaningful use are discussed at section II.2.c of this final rule.⁵

The Final Rule further explains that in Stage 2:

We expect that Stage two meaningful use requirements will include rigorous expectations for health information exchange, including more

² Office of the National Coordinator for Health Information Technology, Health Information Technology: HIT Policy Committee’s Meaningful Use Workgroup Meetings; Notice of Meetings and Request for Comments, 76 Fed. Reg. 1, 2910 (January 18, 2011). Office of the National Coordinator for Health Information Technology, Health Information Technology; Comments Sought on Potential Stage 2 Meaningful Use Objectives, http://healthit.hhs.gov/media/faca/MU_RFC%202011-01-12_final.pdf, at 2.

³ Id. at 10.

⁴ Id. at 11.

⁵ Medicare and Medicaid EHR Incentive Program Final Rule, <http://edocket.access.gpo.gov/2010/pdf/2010-17207.pdf>, at 44321.

demanding requirements for e-prescribing and incorporating structured laboratory results and the expectation that providers will electronically transmit patient care summaries to support transitions in care across unaffiliated providers, settings and EHR systems. Increasingly robust expectations for health information exchange in stage two and stage three will support and make real the goal that information follows the patient. We expect that Stage 2 will build upon Stage 1 by both altering the expectations of the functionalities in Stage 1 and likely adding new functionalities which are not yet ready for inclusion in Stage 1, but whose provision is necessary to maximize the potential of EHR technology. As discussed later in this final rule, we are making some objectives of the Stage 1 of meaningful use optional and other required. We will consider every objective that is CMS-0033-F 36 optional for Stage 1 to be required in Stage 2 as well as reevaluate the thresholds and exclusions of all the measures both percentage based and those currently a yes/no attestation. Additionally, we may consider applying the criteria more broadly to all outpatient hospital settings (not just the emergency department).⁶

Providing interoperable electronic self-management tools to patients with high priority health conditions advances Stage 1 objectives as they were intended in the Final Rule. Specifically the use of these tools will (1) focus on electronically capturing health information in a structured format; (2) use that information to track key clinical conditions and communicate that information for care coordination purposes (whether that information is structured or unstructured, but in structured format whenever feasible); (3) implement clinical decision support tools to facilitate disease and medication management; and (4) use EHRs to engage patients and families and report clinical quality measures and public health information.

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 HITPC to ensure the use of these technologies because they are integral to the achievement of these national goals and priorities. Commercially available technologies

⁶ Centers for Medicare and Medicaid Services, Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Final Rule, 42 CFR Parts 412, 413, 422, and 495.

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, HITPC 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.

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."⁷

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.

If our nation is to develop a system of coordinated care as envisioned in the Affordable Care Act, we must have an electronic exchange of information that goes beyond

⁷ *Id.* at 1951.

providers exchanging information. That exchange of information must also be patient-centered. Stage 2 meaningful use criteria should recognize and foster the patient's role in that exchange, including the use of RPM devices as part of the means to meet the objectives and goals of Stage 2.

Responses to Questions

In the request for comments, the Workgroup asks a number of additional questions. Continua is pleased to provide responses to a number of those questions.

Question: For patient/family access to personal health information, what standards should exist regarding accessibility for people with disabilities (e.g., interoperability with assistive technologies to support those with hearing, visual, speech, or mobile impairments)?

Continua members have designed innovative products in the consumer health space for persons with disabilities. Bringing healthcare devices, applications and services to market for those with disabilities, is important to every member of Continua and should be a key policy goal. Continua appreciates the HITPC's interest in exploring which standards should exist to promote accessibility for people with disabilities, in particular with regards to interoperability of assistive technologies to support those with hearing, visual, speech, or mobile impairments. HITPC should balance any efforts to explore standards for accessibility by exercising a reasonable and flexible approach and avoid mandating standards for devices used by individuals with disabilities that exceed standards which are already readily achievable. Setting rules at this early stage could deter innovations that may revolutionize this particular area of technology later.

Question: What strategies should be used to ensure that barriers to patient access – whether secondary to limited internet access, low health literacy and/or disability – are appropriately addressed?

Barriers to patient access such as limited access to technology, low health literacy and or disability, represent troubling health care disparities in America. The Agency for Healthcare Research and Quality (AHRQ), released two annual reports that address the issues of healthcare disparities and the gaps in care comparing “priority” populations.⁸

In addition to AHRQ, the Federal Communications Commission (FCC) Plan has established the Accessibility and Innovation Initiative which deals with problem-solving among stakeholders to ensure that people with disabilities are not left behind and can obtain the benefits of communications technology.

The Minority Health Office within the Department of Health and Social Services released a joint letter with the National Coordinator for Health Information Technology, Dr. David Blumenthal, on health IT and disparities in racial and ethnic minority groups which

⁸ See, <http://www.ahrq.gov/qual/qdr09.htm>.

remain disproportionately affected by chronic disease.⁹ These efforts in addition to others by the federal government, interest groups and advocates need to become a part of the informed decision making by HITPC on issues of patient access.

Continua urges the HITPC to seek an intra-agency dialogue and approach the issue of patient barriers to access by working with other federal partners that already examine barriers to “patient access.” Too often issues that touch upon several agencies become “siloes” when a true solution to the issues could be developed if all stakeholders could draw upon each other’s experience.

Question: What are providers’ and hospitals’ experiences with incorporating patient-reported data (e.g., data self-entered into PHRs, electronically collected patient survey data, home monitoring of biometric data, patient suggestions of corrections to errors in the record) into EHRs?

Continua represents a broad array of health, technology and medical device companies, including healthcare providers that operate general and long-term acute care hospitals, rehabilitation hospitals, psychiatric hospitals and ambulatory, diagnostic, post acute and extended care facilities. Our members have consistently expressed concern over the initial capital and operating costs associated with deploying EHR’s and their associated systems. In fact, most of our members are grappling with how to remain competitive during tough economic climates while incurring the hundreds of millions of dollars needed to successfully complete their necessary rollout of EHR systems.

As a result, while most provider members are concentrating on the federally promulgated regulations and guidance to develop the interoperable and secure nationwide health information technology network, integrating and incorporating patient-reported data has not been the priority. This includes data self-entered into personal health records (PHRs), electronically collected patient survey data, home monitoring of biometric data and patient suggestions of corrections to errors in the record. While most providers offer sophisticated web based health and wellness engagement tools, online portals and myriad personal health record interfaces, in speaking with our members it is our belief that most providers are only beginning the arduous task with EHR providers to assess how best to integrate those complex patient centered remote monitoring data repositories into their EHR systems. It is not for lack of interest, but rather the priorities on EHR and systems of exchange as stipulated by the ONC’s efforts.

The patient should be the focus of our collective efforts. Data collection should account for clinical requirements as well as biometric patient health data. Incentivizing only those aspects which allow for data exchange and their systems misses the point of facilitating care, and has created a situation where our healthcare providers are more incentivized to exchange data than to make meaningful use of what that data says about the person. Studies demonstrate that patients overwhelmingly favor using remote patient monitoring. A PricewaterhouseCoopers 2009 study of more than 1,000 people reported

⁹ See <http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&objID=3197>

that nearly three-quarters (73%) of consumers said they would use biometric electronic remote monitoring services to track their condition and vital signs.¹⁰

We are dismayed that the proposed language for Stage 3 which includes electronic self-management tools for patients with high priority health conditions, EHRs with capabilities to exchange data with PHRs using standards-based health data exchange, patients provided the capability to report experience of care measures online and capabilities 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, is not being considered in Stage 2. The HITPC should aggressively accelerate its efforts to engage the patient and families in 2013, not 2015 or beyond.

We ask the HITPC to consider that a person's biometric health information, personal health records (PHRs), and any electronically collected data through commercial home-use monitoring technologies, products, devices, sensors and applications be considered for achieving meaningful use in Stage 2, not Stage 3.

Question: What are the reasonable elements that should make up a care plan, clinical summary, and discharge summary?

Charles P. Friedman, the Chief Scientific Officer with the Office of the National Coordinator for Health Information Technology, HHS, recently spoke at the Organisation for Economic Co-operation and Development (OECD) – National Science Foundation (NSF) Workshop about building a smarter health and wellness future through a learning health system.¹¹ Continua agrees with the concept of building a learning health system that contains reasonable elements of health information technologies, throughout the continuum of care. By focusing on the transition of patient care from acute care setting to their home, the handoff process can effectively address problems before patients land back into the hospital.

Continua encourages the consideration of:

- digitizing discharge summaries;
- providing patients with electronic copies of clinical summaries;
- implementing the most applicable form of remote patient monitoring technology at the point of discharge and thereafter as applicable;
- fostering patient engagement through web based tools and other portals;
- building interactive mechanisms to understand how the patient is feeling post discharge;
- focusing on patient education to eliminate obstacles; and,
- identifying high-risk patients for initial increased attention through the use of remote patient monitoring technology.

¹⁰ See <http://mobihealthnews.com/3322/report-73-of-us-wants-to-track-vital-signs/>

¹¹ See http://www.oecd.org/document/55/0,3746,en_2649_33703_46913079_1_1_1_1,00.html

Question: There are some new objectives being considered for stage 3 where there is no precursor objective being proposed for stage 2 in the current matrix. The Health IT Policy Committee invites suggestions on appropriate stage 2 objectives that would be meaningful steppingstone criteria for the new stage 3 objectives.

As we have stated, Continua is encouraged by the HITPC's suggestion to incorporate several aspects that foster patient and family engagement into Stage 3. Unfortunately, we continue to be disappointed that those objectives are not in Stage 2. Specifically, we view electronic self-management tools for patients with high priority health conditions, EHRs with capabilities to exchange data with PHRs using standards-based health data exchange, patients provided the capability to report experience of care measures online and capabilities 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 some of the most meaningful objectives the committee has yet to define. We see no reason for HITPC to consider using precursor objectives for these Stage 3 objectives and recommend that the HITPC either:

1. Accelerate Stage 3 objectives (as defined above in the preceding paragraph) within "Engage Patients and Families in Their Care" as immediate Stage 2 objectives; or,
2. Accelerate Stage 3 objectives (as defined above in the preceding paragraph) within "Engage Patients and Families in Their Care" as immediate Stage 2 objectives with a percentage based goal much like other proposed Stage 2 objectives.

In conclusion, Continua appreciates that HITPC is looking for ways to encourage the use and adoption of health information technologies, which will lead to better care for all Americans.

If we can provide any further information as this process is developed, please do not hesitate to contact Chuck Parker, Executive Director, Continua Health Alliance (chuck.parker@continuaalliance.org).

Sincerely,



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