May 16, 2012

Submitted by email to: HealthIT_CommentPeriod@thune.senate.gov

Honorable Lamar Alexander
Honorable Richard Burr
Honorable Tom Coburn
Honorable Mike Enzi
Honorable Pat Roberts
Honorable John Thune

Re: “Reboot: Re-Examining the Strategies Needed to Successfully Adopt Health IT” (April 16, 2013)

Dear Senators:

In response to your April 16, 2013 public letter invitation and your “Reboot” white paper captioned above, our Healthcare Innovation Council is pleased to submit our attached response entitled “Let’s Admit the Emperor has No Clothes—It’s Time to Redesign EHRs to Improve Patient Care.” We hope that our commentary will help expedite a critically needed change in direction for the “meaningful use” stimulus program for electronic health records. The members of our Healthcare Innovation Council, who are identified in our attached response, would welcome the opportunity to discuss our commentary with you in more detail if that would be helpful. Thank you for the opportunity to express our views regarding this extremely important issue facing our healthcare industry.

Very truly yours,

HEALTHCARE INNOVATION COUNCIL

By, 

Richard K. Kneller
Chairman
Let's Admit the Emperor Has No Clothes- It's Time to Redesign EHRs to Improve Patient Care

A public commentary from Anthelio's Healthcare Innovation Council

Anthelio’s Healthcare Innovation Council is an independent group of healthcare experts that generates and publicly shares innovative ideas about how U.S. hospitals and healthcare providers can meet escalating quality and financial pressures.

Abstract: Congress allocated $30+ billion of taxpayer monies to stimulate adoption of electronic health records (“EHRs”) by hospitals and physicians in order to improve healthcare quality. With nearly half of those monies spent, EHRs have not produced meaningful improvements in patient care and instead have made it more, rather than less, difficult for clinicians to provide patient care. It is time to redo the “meaningful use” EHR stimulus program to ensure that EHRs are designed and implemented in ways that help them improve patient care quality, safety and efficiency. Unless that is done, we then urge Congress to halt CMS’ “meaningful use” EHR program and spend the remainder of the “meaningful use” funds on providing financial incentives for hospitals and other providers that demonstrate “meaningful improvements in patient care” through whatever means they choose.

There’s always wisdom in asking the question “if I knew then what I know now, what would I do differently?” This question might be particularly instructive in looking at the substantial amount of resources—both dollars and people—we have invested in electronic health records (EHRs) over recent years and the EHR promise to deliver better patient care.

In 2009 Congress allocated $30+ billion of our taxpayer monies in the American Recovery and Reinvestment Act (ARRA) to stimulate adoption of EHRs and create a nationwide health information technology (HIT) infrastructure. The stated purpose of the HIT infrastructure was “to improve the quality of health care, such as by promoting the coordination of healthcare and improving the continuity of health care among providers by reducing medical errors, improving population health, reducing health disparities, reducing chronic illness, and advancing research and education.” The lofty goals for these EHR stimulus monies also included providing clinical decision support, supporting physician order entry, capturing/querying healthcare quality information, and exchanging/integrating such information among healthcare providers.

Whew! Lofty goals indeed! And thus far the Centers for Medicare & Medicaid Services (CMS) has spent over $12.7 billion of EHR stimulus monies.

Are we getting our money’s worth from such a huge investment of taxpayer dollars? Why are we, both as healthcare providers AND as consumers of healthcare (as well as
taxpayers), not seeing noticeable improvements in quality, coordination, continuity and improved process from providers who have implemented EHRs? Instead what we are seeing is a massive disruption of providers' patient care focus as they chase “meaningful use” dollars; increased burdens on physicians, nurses and clinicians since EHRs as currently designed require more, not less, of their time and effort; and an unprecedentedly huge expenditure by providers on EHR hardware and software at a time when providers are under severe financial pressures.

HAVE WE LOST TRACK OF THE PLOT? IS IT TIME FOR A DO-OVER?

We believe that the root cause reasons why EHRs aren’t delivering on their promises include:

- **EHR design issues**: EHRs, to date, have been fundamentally designed to create electronic versions of paper medical records. EHRs focus on data collection mostly for regulatory compliance and financial reporting, not to assist physicians, nurses and other clinicians in providing higher quality more efficient patient care. As a result, the EHRs are not designed to reflect or facilitate the way in which providers deliver patient care, and thus disrupt, rather than enhance, patient care; and

- **EHR implementation issues**: EHR implementations are often led as IT "projects" by teams that do not obtain robust, meaningful, future-focused input/involvement from nurses, physicians, pharmacy and other clinicians who provide patient care. The end result typically is that EHR implementations don't make life better for EITHER the clinician or the patient. Sadly, more often than not physicians, nurses and other clinicians find EHRs make it more, rather than less, difficult to provide better patient care.

So, from the "if I knew then, what I know now perspective", we've had numerous conversations with a wide array of clinicians from multiple hospital, academic and provider practices, all of whom are using EHR systems from the leading EHR vendors (e.g., Epic, Cerner, Siemens, McKesson, Meditech etc.). The following themes emerged from those discussions, which question the ability of the current breed of EHRs to improve patient care and question the implementation methodology used by many providers that doesn't have sufficient focus on improving patient care:

- Improving patient care should have been the primary focus for EHR planning/implementation, as directed by Congress in the ARRA. Instead, CMS' and healthcare providers’ focus has been to "just get EHRs up and running" in a way that meets CMS' "meaningful use" requirements so that they can get "meaningful use" dollars, without regard to how that affects patient care. CMS should change its "meaningful use" requirements to require measureable improvements in patient care in the short-term.
• The primary caregivers, nurses, were often not involved in EHR planning or had limited involvement with boundaries and limitations when nurses identified specific patient care needs.

• EHR planning was primarily from the IT perspective, not from the clinical care perspective.

• The EHR was not designed to provide a longitudinal view of the patient’s story over a period of time, with trending capabilities for improved decision making.

• The EHR is cumbersome and requires too many clicks to obtain needed patient information.

• The EHR does not facilitate patient knowledge, education or input.

• Quality of documentation has decreased, not increased, after EHR implementation.

• The EHR is primarily an electronic documentation tool that unfortunately also isn’t, but could be, a "brain partner" decision support tool that aids clinicians in providing and improving patient care.

• EHRs should be interoperable so that EHR patient records are accessible to all care givers (subject to appropriate security and privacy), which was another direction to CMS by Congress in the ARRA.

• The efficiency and effectiveness of care delivery business processes need to be reviewed and re-engineered prior to, not after, commencement of the EMR implementation.

These indictments of both our current breed of EHRs and the way in which EHRs are being implemented cry out for change in direction of the “meaningful use carrot” in CMS’ program that has already cost taxpayers $12.8 billion and cost healthcare providers tens of billions.

**ESCALATING VIEW THAT THE EMPEROR HAS NO CLOTHES**

A growing chorus of experts is beginning to question whether CMS’ EHR program is misdirected and not likely to achieve its objectives within a reasonable period of time. Consider the following:

• The first significant voice to challenge the direction of EHRs came way back in December 2010 when President Obama’s Council of Advisors on Science and Technology called for a change in the direction for EHRs since “[s]everal identifiable barriers in the healthcare system currently discourage innovation and vigorous competition in the market to create effective health IT systems”,


including that “most current health IT systems are proprietary applications that are not easily adopted into the workflow of a clinician’s day, and whose proprietary data formats are not directly exchangeable from one system to another.” The Council bluntly urged a major change in CMS’ HITECH approach to stimulate the widespread adoption of EMRs/EHRs, which it said “creates a danger that EHR adoption during early stages of meaningful use may exacerbate the problem of incompatible legacy systems.”

- A 2011 letter to the ONC from 39 different physician professional organizations raised serious concerns regarding EHRs and interoperability technology issues: “Asking physicians to do more within an environment that is still not largely interconnected, and in which commercially available products cannot perform the required functions reliably, will simply result in additional financial and administrative burdens, including the use of time-consuming dual processes—paper and electronic....”

- In January 2011 Stanford University researchers Max J. Romano, BA, and Randall S. Stafford, MD, PhD. published a paper that also challenged the CMS push for EHRs since they found no evidence that EHRs would have any meaningful impact on healthcare quality: “despite the promise of better quality, the clinical benefits of EHRs and CDS [clinical decision support] are not evident in our quality indicators...our results raise doubts about past implementation of costly EHR technologies nationally. While EHRs offer substantial administrative efficiency over paper records, current patterns of EHR and CDS use do not appear to translate into better outpatient quality of care.”

- In November 2011, the Institute of Medicine released its latest report entitled “Health IT and Patient Safety: Building Safer Systems for Better Care” that bluntly stated that “the current state of safety of health IT must not be permitted to continue....Evidence suggests that existing health IT products in actual use may not yet be consistently producing the anticipated benefits, indicating that health IT products, in some cases, can contribute to unintended risks of harm...Health professionals require technologies that make this work easier and safer, rather than more difficult...Many health information systems used today provide poor support for the cognitive tasks and workflow of clinicians....This can lead to clinicians spending time unnecessarily identifying the most relevant data for clinical decision making, potentially selecting the wrong data, and missing important information that may increase patient safety risks.”

- In January 2013, the RAND Corporation released an updated report on EHRs that was a stunning reversal of its earlier report (skeptics allege that the earlier report was biased in favor of EHRs since it was financed by EHR software companies): "Health Information Technology systems must be engineered to aid the work of clinicians, not hinder it. Systems should be intuitive, so they can be used by busy health care providers without extensive training. Doctors and other healthcare providers should be able to easily use systems across different health care settings, much as consumers easily drive various makes and models of automobiles.”

- On January 14, 2013 the American Medical Association (“AMA”) challenged the ONC’s ongoing rush to incentivize/force adoption of EHRs: “While the AMA
shares the Administration’s goal of widespread EHR adoption and use, we are extremely concerned with the recommended approach to move full speed ahead without a comprehensive evaluation of the program and resolving existing barriers, including Health IT infrastructure flaws.”

- In 2013 CRICO, a patient safety and medical professional liability company owned by and serving the Harvard medical community, stated that that traditional EMRs don’t help clinicians improve patient care quality: “Traditional EMRs, evolved from hospital billing systems, provide a wealth of information and data, but fall short of helping clinicians streamline significant administrative requirements or process the vast amounts of information needed to care for patients. Nor do they reduce risk by helping avoid the types of oversights that can lead to an adverse event.”

- On April 25, 2013 ONC announced that it had revoked the certifications of two EHR products that previously had been certified under the “meaningful use” program. This is the first time that has happened and has caused huge concerns among hospitals and physicians about the possibility that more de-certifications could follow and disrupt EHR implementations and “meaningful use” funding.

It’s clearly time for Congress to reconsider whether CMS’ “meaningful use” program is furthering Congress’ explicit ARRA goal to employ EHRs to improve patient care. When Congress decided to rely on CMS and ONC to promulgate rules to achieve that goal, Congress was warned that it ought to exercise ongoing oversight to ensure that the federal ARRA stimulus monies would be used to improve patient care and quality. Specifically, on June 26, 2009 a Congressional Health Care Caucus panel presentation moderated by Representative Michael Burgess, M.D., Chair of the Caucus, with the following panel participants, stated that EHRs were not focused on improving patient care and quality, and thus urged that Congress not allow CMS to pay “meaningful use” funds to implement those EHRs without a focus on patient care and quality—the panel participants included Dr. Herbert Lin, Chief Scientist at the National Research Council and Editor of its report entitled “Computational Technology for Effective Health Care—Immediate Steps and Strategic Directions”; Tevi Troy, former Deputy Secretary of HHS; and Rick Kneipper, Co-Founder of Anthelio Healthcare Solutions and a member of Anthelio’s Healthcare Innovation Council.

Unfortunately, that warning wasn’t heeded, but fortunately some in Congress are starting to listen to the rising crescendo of concerns about CMS’ “meaningful use” EHR program since on April 16, 2013 Senators Thune, Alexander, Roberts, Burr, Coburn and Enzi issued a report entitled “Reboot: Re-Examining the Strategies Needed to Successfully Adopt Health IT” that stated as follows:

“[W]hile promoting the use of health IT is a laudable goal, a growing body of objective analysis and empirical data suggests that the [HITECH “meaningful use” stimulus] program needs to be recalibrated to be effective. Congress and the administration need to work together to ‘reboot’ the program to accomplish the aims of meaningful use and interoperability and ensure appropriate stewardship of taxpayer dollars in the process.”
REDESIGNING EHRS TO IMPROVE PATIENT CARE

As Steve Jobs taught the world, design simplicity should be linked to making products easy to use—“The main thing in our design is that we have to make things intuitively obvious.” The problem is that EHRs as currently designed are neither simple to use nor intuitive, and in fact make patient care more difficult and time consuming.

If we rethink design from the users’ perspective, we believe it is essential that physicians and nurses, who are widely recognized as the primary caregivers and serve as 24X7 advocates in coordinating care across the team of providers, take a more central and meaningful role in the selection, design, implementation and operation of EHRs. In the day of manual records, nursing notes, for example, would be stored away in the Medical Records Department, and, for the most part, ignored except for necessary discharge planning. The electronic record is changing that equation. Increasingly, data stored electronically will become available to identify population health patterns of care and outcomes for large groups of people. In order to deliver improved population health, it is critical that nurses and doctors take an active EHR design role, both for care and for research and outcome improvement. Nurses are where the proverbial rubber meets the road in patient care. If EHRs are designed and implemented to simply and conveniently deliver what nurses need and when they need it, patient care, along with patient experience, would be dramatically improved. Unfortunately, more often than not, nurses are not meaningfully tapped for a strong EHR design or implementation role, and neither are other caregivers, including physicians, pharmacists etc. This is a missed opportunity that needs to be remedied.

Healthcare is a relationship business first and foremost. Technology should enable and enhance that relationship— not inhibit or replace it.

Strong nurse, physician and clinician EHR involvement will help achieve the following patient care improvement objectives:

- Improved focus on EHR design and implementation that starts by mirroring the way care is actually delivered by nurses, doctors and other clinicians. This basic design then would move to new, information enhanced processes that not only help clinicians do their jobs easier, but measurably improve patient care safety and quality.

- Discovery and integration of ways to enable a richer, more engaged and meaningful patient/caregiver relationship versus one that requires increased clinician time for record keeping instead of patient care.

- Redesigned EHR processes that ensure nothing falls through the cracks in care transitions (e.g., medication reconciliation,) which are a major source of patient safety issues.
• Rethinking, redesigning and re-engineering nurse, physician and clinician workflows to take full advantage of the capabilities of the new (and evolving) EHR tools to result in improved healthcare processes and care experiences.

It is important to recognize that EHR design does not end with implementation. Nurses and other clinicians should continue to play an active role in continually optimizing the EHR tool based on experience gained from its use. The vision of the EHR should be tempered by its use, and refined and enhanced as needed. That is the only way to ultimately deliver on the lofty promises made and demonstrate the full value of the tool to clinicians and patients.

TIME TO REDEFINE MEANINGFUL USE

The flaws of designing EHRs to capture data without improving patient care could be addressed if CMS “reboots” by refocusing its “meaningful use” stimulus monies to ensure that EHRs are designed and implemented in ways that demonstrate improved patient care, improved caregiver efficiency and improved patient experience. This is what CMS was charged to do by both Congress and the ARRA. We believe that CMS' top priority should be requiring that EHRs provide real and measurable benefit to users and make a positive difference to patient care. Let's count what counts- not merely what we can count.

Actual patient care improvement and better patient care process are not, but need to be, key parts of CMS' “meaningful use” criteria. Increased nursing and physician clinical input will improve EHR design, acceptance and outcomes, as well as improve resource utilization and effectiveness of patient care resources. In order to ensure this clinician input, “meaningful use” criteria should require, and measure, (i) the involvement of caregivers, nurses and physicians in the EHR design, implementation and utilization processes and (ii) the post-implementation effects of the EHR on achieving meaningful patient care improvement. This would change CMS’ “meaningful use” standard to a “meaningful use in improving patient care” standard in order to achieve a continuous patient care, quality, safety and outcomes process improvement.

SUCCESS

It’s time to reassess the mad race for “meaningful use” dollars that CMS has fostered. CMS' program is not resulting in EHRs that improve patient care, as mandated by Congress when it created and funded the program. CMS needs to change its “meaningful use” criteria to ensure that providers implement EHRs in ways that improve patient care. Moreover, requiring providers to move from one EHR project to another EHR project at breakneck speed does not allow for the optimization of what was just finished before attention goes to the next big thing, and has resulted in huge numbers of EHRs that are “in the ditch” and interfering with, not facilitating and improving, patient care. And CMS’ rush for EHRs does not appropriately recognize the overwhelming need for healthcare providers to concentrate on the multiplicity of unprecedented financial, clinical and political challenges they are facing today.
We squander and disrespect the wisdom of our users when we treat them solely as operators of our electronic tools. Steve Jobs did not do that—there’s magic in that wisdom. Our users, medical professionals, are hungry for ways to improve patient care quality, efficiency and costs, and it’s time to redo the “meaningful use” EHR stimulus program to ensure that EHRs are designed and implemented in ways that help them improve patient care quality, safety and efficiency. It’s time to “reboot” before all of the “meaningful use” monies are spent and make that happen. Unless that is done, then we urge Congress to halt CMS’ “meaningful use” EHR program and spend the remainder of the “meaningful use” funds on providing financial incentives for hospitals and other providers that demonstrate “meaningful improvements in patient care” through whatever means they choose, and leave it to the healthcare providers, not our federal government, to choose the most effective means to improve patient care.

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Anthelio’s Healthcare Innovation Council members are:

- **Robert Burns, PhD, MBA**: Chair of the Health Care Management Department at Wharton School, University of Pennsylvania; Director of the Wharton Center for Health Management and Economics
- **Hud Connery, MHA**: CEO of iVantage, a healthcare data analytics company; former founder and CEO of Essent Healthcare, a for profit hospital company
- **Kevin Hickey**: Founder and Principal with HES Advisors, a consultancy to healthcare growth companies; former executive roles with Oxford Health Plans, Aetna, Lincoln National and MetLife
- **Julie Klapstein**: Former founding CEO and Vice Chair of Availity, a health information network; board member of Annies Organics, Standard Register, Dominion Diagnostics and Akal
- **Rick Kneipper**: CEO (Interim), Chief Strategy and Innovation Officer, and Co-Founder of Anthelio Healthcare Solutions
- **Jack Lord, MD**: Former COO of University of Miami Health System; former CEO, Navigenics; former SVP and Chief Innovation Officer, Humana Inc.; and former COO, American Hospital Association
- **John McConnell, MD**: CEO, Wake Forest Baptist Medical Center; EVP for Health Affairs, Wake Forest University; Professor of Urology, Wake Forest University School of Medicine; former EVP for Health System Affairs at University of Texas Southwestern Medical Center; elected to Institute of Medicine of the National Academy of Sciences
- **Sharon Riley**: Former CEO of University of Texas Southwestern Medical Center University Hospitals; former COO of Anne Arundel Medical Center; former COO of University of Nebraska Medical Center; Board member of Heska Corp.; Senior Advisor to DigiWorks
- **MaryAnn Stump, RN, MBA**: Former SVP, Chief Strategy and Innovation Officer, Blue Cross and Blue Shield of Minnesota; External Advisory Board, Yale College of Nursing; Robert Wood Johnson Foundation Executive Nurse Fellow National Advisory Board

With special thanks to **Jack Kowitt**, Executive Vice President of Anthelio Healthcare Solutions (former CIO of Parkland Health & Hospital System), who participated in the preparation of this commentary.

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