May 20, 2013

The Honorable John Thune
United States Senator
511 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Lamar Alexander
United States Senator
455 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Pat Roberts
United States Senator
109 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Richard Burr
United States Senator
217 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Tom Coburn
United States Senator
172 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Michael Enzi
United States Senator
379A Russell Senate Office Building
Washington, D.C. 20510

Senators Thune, Alexander, Roberts, Burr, Coburn and Enzi:

Thank you for the opportunity to comment on the April 16, 2013 report entitled "Reboot; Re-examining the Strategies needed to Successfully Adopt Health IT".

Health IT Now (HITN, www.healthitnow.org) is a diverse coalition of health care providers, patient advocates, consumers, employers and payers who support the adoption and use of health IT to improve health care and to lower costs. The comments in this letter reflect those of Health IT Now, and not necessarily those of our individual members.

In the report, we believe you have identified legitimate concerns about federal health IT policy. HITN is likewise concerned that many of the policies pursued by the Administration are demonstrating low value and can be substantially improved. Several deficiencies stem from the governing statute's weak requirements to ensure systems are interoperable and used in a way that maximizes efficiency and effectiveness in Medicare and Medicaid. Lack of robust program standards is likewise eroding trust that program dollars are being spent well. Finally, we are concerned there is little linkage between Meaningful Use and other federal payment and delivery structures that might create a better business case for the adoption and use of health IT.

We offer our suggestions as part of an ongoing, constructive dialogue to help ensure taxpayers, providers and patients receive better value through the various health IT programs. We believe Congress should revisit the HITECH statute and make program improvements to address many of the issues outlined in your report. We outline our suggestions below, but briefly we suggest Congress should:

1. **Not pause or delay the Meaningful Use program.**

2. **Revise the HITECH law to require robust interoperability by 2018. Congress should provide funds to assist HHS in meeting this goal.**

3. **Require interoperability standards to be backwards compatible to recognize market evolution and the technologies already adopted by many providers.**

4. **If HHS fails to address information blocking in the extension of the expiring Stark exception and Anti-Kickback safe harbor for donated health IT, Congress should end the practice.**

5. **HHS should end attestation in the Meaningful Use program through the physician and hospital payment rules. If HHS fails to act, Congress should end self-attestation by amending the HITECH law.**

6. **Congress should fold health IT incentives into the basic payment structures for providers in Medicare and Medicaid.**

THE VALUE OF HEALTH IT

Health IT Now strongly supports the Meaningful Use program, but we believe there are appropriate changes to be made that will enhance its effectiveness and capitalize on its potential.

In 2005, the RAND Corp., a not-for-profit institution that provides research on various public policy topics, published an analysis estimating that EHR adoption has the potential to save $81 billion a year provided the technology is interoperable. When RAND recently released a follow-up study, analysts found their original cost-savings estimates have not come to fruition. Dr. Art Kellermann, the RAND study's senior author, stated, "The failure of health information technology to quickly deliver on its promise is not caused by its lack of potential, but rather because of the shortcomings in the design of the IT systems that are currently in place." Health IT Now would take Dr. Kellermann's statement a step further and argue that the design of the IT systems are not the problem; it is the standards in the federal incentive program that have failed to meet RAND's caveat: We are not close to a truly interoperable IT infrastructure.

What we know from the recent RAND analysis is what we knew from the original research: without an interconnected, interoperable infrastructure, realized savings will not materialize. Put another way, we know that the lack of interoperability is a key factor in limiting the effectiveness of EHRs. In addition, the current federal programs are often burdensome on providers, lack flexibility and are managed across multiple Departments and Agencies. This is unfortunate because health IT can create major efficiencies in Medicare and Medicaid. For example, there are dozens of studies documenting health IT's ability to reduce duplicate tests and expensive hospitalizations while improving care coordination and outcomes. [1] Finally, Congress

[1] References to a few studies:

is contemplating reforms to Medicare's physician payment model and other payment systems. It is simply not practically feasible to pay providers on value without health IT's ability to track, document and measure service quality and efficiency.

With minor changes in the course of federal policy, we believe health IT holds vast potential to wring tens of billions of dollars in inefficiencies out of our bloated healthcare system. We encourage you to keep this in mind as Congress contemplates changes to various federal health IT programs.

THE PATH TO INTEROPERABILITY

Establishing Goals and Meeting Them

We agree with your statement in the Reboot report and with the HHS Inspector General[2] that the large sum of taxpayer resources spent on the Meaningful Use program is at risk. We are concerned there is little direction or a final objective embedded in federal policy and operationalized by regulators.

HITN strongly supports the vision of an information-rich, person-centered, high performance health system where, "…every health care provider has access to longitudinal data on patients they treat to make evidence-based decisions, coordinate care and improve health outcomes." This vision was recently issued by the Department of Health and Human Services in an RFI on fostering interoperability through federal programs.[3]

The HITECH Act's Meaningful Use Program has facilitated the adoption and use of EHRs by more than half of all hospitals and physicians by providing $27 billion over ten years through Medicare and Medicaid. As you note in the Reboot Report, healthcare providers must meet federal standards, which are being implemented in phases over several years, in order to qualify for incentives. Each Stage builds on the prior stages in expanding beyond transactions and automation to use for clinical decision support and patient outcomes.

- Case Study: Collaborative Cardiac Care Service – Collaborative Teams Improve Cardiac Care with Health Information Technology, Kaiser Permanente, available at http://xnet.kp.org/future/ahrstudy/032709cardiac.html. The study found CCCS participants were an average $60 less per day than the other group, or about $21,900 less per patient annually (Merrill, *Healthcare IT News*, 10/25).
- Electronic Medical Records and the Efficiency of Hospital Emergency Departments**,** Med Care Res Rev, February 2011, 68: 75-95,first published on June 16, 2010
- A study conducted by Kaiser Permanente's Institute for Health Research of more than 788,000 patient visits in eight primary care clinics of Kaiser Permanente's health care system in Colorado found that real-time physician alerts reduced unnecessary use of a blood test used to help diagnosis blood clots in elderly patients.http://www.healthdatamanagement.com/news/study-blood-clots-tests-alerts-kaiser-41304-1.html
- Trappenburg et al. (2008), looked at remote monitoring for lung disease and found hospitalizations were reduced by 41 percent versus control.

[2] HHS Office of Inspector General, *Early Assessment Finds that CMS faces Obstacles in Overseeing the Medicare EHR Program*, OEI-05-11-00250, November 2012, available at https://oig.hhs.gov/oei/reports/oei-05-11-00250.pdf

[3] Notice for Comment, Request for Information on advancing interoperability and health information exchange published in the Federal Register on March 6, 2013 (BILLING CODE 4150-45-P)

HITN believes the Meaningful Use Program is making progress in automating the existing health system and achieving operational efficiencies. The MU Program has moved the ball forward in digitizing physician offices and automating the current paper-based system. Automation is an important step to evolve the health care system, but it has not transformed; rippled, but not disrupted. The vision of a technology-enabled health system is where devices, systems, and modules enable patients and providers to interact in the health system with the tools and information necessary to be engaged in their health and live healthier lives. To achieve the vision requires an architecture and roadmap that clearly outlines the characteristics of the transformative system and how to measure progress to the goal.

Measuring if are we better than yesterday is fine for incremental improvement. Measuring to a vision and defined goal is transformative. **We believe Congress should modify the HITECH act to require that by 2018 we will have a technology-enabled health system which supports coordinated care, expansive research and development of new treatments, provider skills and abilities. We suggest adopting the HHS vision as a requirement to be achieved by HHS by 2018.** Having this goal means HHS can operationally work backwards to determine the specific steps necessary to meeting the goal within the timeframe. Likewise, providers and patients will know that by a date certain, interoperability in health care will be a reality, not a hope.

Finally, in order to carry out this mission, we believe ONC needs additional resources and expanded authority to drive change across Departments and agencies. We suggest Congress allocate funds to this end.

Recognizing a Diverse Market

We also agree with the statement in the Reboot Report that requirements applied uniformly and on the same timeline to all providers ignores that many providers have unique challenges and needs. One example is the emergence of the Direct standard as the transport protocol in Stage 2. Direct was not a market contrivance, but was rather developed by ONC and industry to facilitate basic exchange via secure email.

While the Direct protocol may be desirable in certain ways because of its greater potential for adoption, requiring it as an exclusive standard frustrates providers who are already using alternate standards. This policy devalues the time and resources many have made in moving beyond simple point-to-point messaging, forcing them to redesign their more robust systems. While rapidly implementable, the Direct standard, even with new query functionality required for Stage 2, is minimally scalable and would likely lack the data liquidity necessary to enable health IT dependent models, such as ACOs and medical homes. In addition, the Direct standard is good at sending discrete information, but it simply does not deliver the aggregated information necessary to assist the delivery of care in coordinated settings. This creates patient safety issues since one clinician's view of the patient encounter may be limited. A summary of care record established at the local HIE level could provide a better, more up-to-date view of a patient's history.

So while Direct is an important step in fostering information sharing between providers, Direct should be a floor, not a floor and a ceiling. **We encourage Congress to require that interoperability standards are backwards compatible to Direct, just as Congress did in the Medicare Modernization Act for standards related to e-prescribing.** Doing so would allow health care providers to use transport standards that allow both sharing and querying of data residing in multiple locations. Backward compatibility standards allow the market to evolve without federal rulemaking, but they still support the approach ONC and CMS are pursuing in Meaningful Use.

Information Blocking

The Reboot report identifies anecdotal reports of some EHR vendors who use contracts to block or require increased resources for the exchange of data from competitors. We suggest these business practices are also employed by healthcare providers and are troubling. CMS notes this is a major problem in the Stage 2 Final Rule, but is only monitoring the situation and not taking action to address this problem until 2016 at the earliest. As ONC stated in a recent podcast linked and referenced here (and paraphrasing the final rule): "we will pay close attention to whether the requirements in the rule are sufficient to make vendor-to-vendor exchange attainable for providers. If there is not sufficient progress or we continue to see barriers that create data silos or 'walled gardens,' we will revisit our meaningful use approach and consider other options to achieve our policy intent". Meanwhile, taxpayers are subsidizing business practices in an information sharing program that blocks information.

Information blocking also erodes provider trust in the systems they use and leads to unsafe clinical environments because partial information on a patient leads to medical errors and adverse events.

We suggest information blocking is not acceptable. **While we believe HHS can address this problem this year through an extension of the expiring Stark exception and Anti-Kickback safe harbor rules, if the Department does not, we strongly encourage Congress to amend the fraud and abuse laws to make these business practices obsolete.** The Stark and Anti-Kickback proposed rules have been issued, and should be finalized by the end of 2013.[4]

Specifically, we suggest expanding the current condition to prohibit actions that limit or restrict the use, compatibility, or interoperability of the items or services with *other health information technology*. Expanding this language beyond the current Stark and Anti-Kickback rule's focus on electronic prescribing and electronic health records systems reflects the rapidly shifting nature of today's technology to go beyond the care of an individual and manage quality and cost efficiencies across populations. Second, we suggest making clear that neither the donor nor donee can take any actions to limit the interoperability of donated health information

[4] On April 10, CMS released a proposed rule that would revise the exception to the physician self-referral prohibition for certain arrangements involving the donation of electronic health records items and services. On the same day, the HHS Inspector General issued a proposed rule to amend the safe harbor regulation concerning electronic health records items and services, which defines certain conduct that is protected from liability under the Federal anti-kickback statute. The OIG rule is available here [pdf]. The CMS rule is available here [pdf].

technology. To this end, HHS should establish a new condition under the exception and safe harbor that clarifies the prohibition against data "lock-in" and require that any written agreement subject to the exception and safe harbor incorporate this new condition.

OVERSIGHT

We share your concerns as outlined in the Reboot report and echoed by the HHS Inspector General that self-attestation is a key vulnerability of the program. Over the life of the Meaningful Use incentives, taxpayers will spend tens of billions of dollars to encourage providers to adopt electronic systems. There are a number of pay for value programs in the commercial sector, and the best ones do not rely on self-attestation. They are audited and investigated to ensure performance matches documentation. The reason that self-reporting is not used is to avoid misreporting achievement or attainment of quality status in order to earn an incentive.

HHS should end attestation in the Meaningful Use program through the physician and hospital payment rules. If HHS fails to act, Congress should end self-attestation by amending the HITECH law. CMS should be granted rigorous audit rights so that the agency can ensure it is making properly earned payments. These rights should include audit and investigation rights into the accuracy of the data submitted by the EHR itself, and the accuracy of the information attested to by the physician.

DATA SECURITY

We are encouraged that, as technology becomes more sophisticated, solutions are available that more securely protect electronic information. We note the advances made in the last few years related to encryption and key management, user and sender authentication and usage and access enforcement. We believe these technology solutions address the issue raised in the Reboot Report related to striking a balance between securing data and burden on vendors and providers. We believe HHS should more aggressively promote these technology solutions via standards across programs that require sharing of potentially sensitive health and other information.

LONG TERM SUSTAINABILITY

We understand your concerns raised in the Reboot report that over the long term, providers may face sustainability challenges, especially as bonus payments turn into penalties. In other industries, the key to improving quality, outcomes and costs rests in an organic (self-organizing) business case for use of technology to improve value (cost and quality) and to become more productive (output and cost). We believe that the U.S. health care system lacks a compelling business case to improve value or productivity. Many aspects of our current health care system encourage inefficiency, promote waste and facilitate concentrated and consolidated markets aided and abetted by data silos. Sustainability questions related to adoption and use of health IT suffers from the system-wide lack of a business case to become more efficient while delivering higher quality services. HITN believes the movement to rewarding value and at-risk payment and delivery models are beginning to shift the business case, and that this will have a

positive impact on the adoption and use of health IT. Our concern is that if health IT tools are incapable of supporting providers in these models, years of lost cost saving opportunities will accrue.

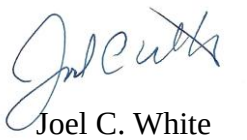
We encourage Congress, as it considers, develops and creates legislation to reform Medicare and Medicaid, to fold health IT incentives into the basic payment structures of providers. Doing so will integrate incentives to use technologies to improve care and lower costs. Health IT is a tool, like any other. If the underlying system promotes efficiency and effectiveness, integrating IT into the system should make the tool an effective weapon against wasteful and clinically redundant or harmful care. We encourage Congress to adopt this approach as part of any proposal to rework federal health program payment and delivery models. We believe this approach will make the business case for providers to employ technology productively, which in turn will begin to address the seemingly intractable problems of cost, quality, outcomes and safety endemic in American health care.

CONCLUSION

In the Reboot report, you ask the question of whether it would be in the best interest of all to "hit pause" in forging ahead with Stages 2 and 3 of the program. We believe the answer is no. There are certainly problems evident in Meaningful Use. No program is perfect. But as this letter indicates, there are discrete and practical solutions the Administration and Congress might adopt to refine the program and improve its deliverables. We suggest a fundamental reordering of priorities and refocusing actions to execute on those priorities rather than hitting "pause" in implementing the program. Others suggest different approaches. Reaching consensus on a shared goal will not be difficult, however, because most agree interoperability is the prize. We will almost certainly disagree on how to achieve interoperability. Building consensus on how to get there is a leadership challenge.

We thank you for your leadership on these issues, and for highlighting them in the Reboot Report. We look forward to working with you to ensure the federal health IT programs are delivering real value to taxpayers, patients, providers and payers.

Sincerely,



Joel C. White
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