



May 16, 2013

Submitted Electronically to HealthIT_CommentPeriod@thune.senate.gov

The Honorable John Thune
United States Senator
511 Dirksen Senate Office Building
Washington, D.C. 20515

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

The Honorable Lamar Alexander
United States Senator
455 Dirksen Senate Office Building
Washington, D.C. 20515

The Honorable Tom Coburn
United States Senator
172 Russell 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 Mike Enzi
United States Senator
379A Russell Senate Office Building
Washington, D.C. 20510

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

Thank you for the opportunity to comment on this important report. We are committed to advancing the use and exchange of electronic health information through interoperable health technologies in secure, privacy-protective ways, and we appreciate that you share these goals.

The Center for Democracy & Technology (“CDT”) is a non-profit Internet and technology advocacy organization that promotes public policies that preserve privacy and enhance civil liberties in the digital age. As information technology is increasingly used to support the exchange of medical records and other health information, CDT, through its Health Privacy Project, champions comprehensive privacy and security policies to protect health data. CDT promotes its positions through public policy advocacy, public education and litigation, as well as through the development of industry best practices and technology standards.

Recognizing that a networked health care system can lead to improved health care quality, reduced costs and empowered consumers, CDT is using its experience to shape workable privacy solutions for a health care system characterized by electronic health information exchange.

CDT is frequently relied on for sound policy advice regarding the challenges to health privacy and security presented by health information technology (health IT) initiatives. We have testified before the U.S. Congress seven times since 2008 on the privacy and security issues raised by health IT, and we chair the privacy and security policy working group of the federal Health IT Policy Committee (called the “Tiger Team”).

Through our involvement with the Health IT Policy Committee in particular, we have been deeply engaged in the implementation of the HITECH Act, which we supported not only for the transformational investment it made in the adoption and implementation of electronic health record (EHR) technology, but for the important and positive steps it took toward closing gaps in federal privacy protections for health data. From the enactment of HITECH through the inception of the regulatory process for Stage 1 of Meaningful Use, we have applauded policymakers – Congress and the Department of Health and Human Services (HHS) – for establishing an important and ambitious set of priorities, simultaneously emphasizing rapid progress and broad participation.¹

In addition to the comments submitted by the Consumer Partnership for eHealth (CPeH), which we joined, we offer our own comments in three of the five areas you outline in your White Paper:

1. Interoperability;
2. Oversight; and
3. Patient privacy.

I. Interoperability and Exchange of Health Information

We agree with you that interoperability is the “key to achieving efficiencies in care with health IT,” and in addition that it is key to achieving improved care coordination, communication between patients and their care team, and health outcomes. We also agree with you that interoperability has, to date, proved difficult to establish, and that the Meaningful Use incentive program currently has too few information exchange requirements. We bring to your attention the

¹ See Markle Connecting for Health, Collaborative Comments on the Centers for Medicare and Medicaid Services’ Notice of Proposed Rulemaking for the Electronic Health Record Incentive Program, *available at*: http://www.markle.org/sites/default/files/20100315_ehrincent_cms0033p.pdf.

exchange capabilities that the program *does* require and the advancements proposed by the Health IT Policy Committee for Stage 3, which are not mentioned in the report. We also note that Stage 2 EHR certification requirements expressly require testing for interoperability.²

A. Necessity of a Balanced Approach to Meaningful Use

Given the substantial taxpayer investment made in this incentive program, duly noted in the report, the Meaningful Use program should be a strong “push” to get health care organizations to move forward at a much faster pace than would be the case absent incentives. The white paper cites the Congressional Budget Office (CBO) report that predicted 45 percent of hospitals and 65 percent of physicians would have adopted health IT by 2019 without the incentive program. This is precisely why the incentive program is necessary. Congress recognized in enacting HIECH that patients cannot wait that long for the health care system to improve and modernize. The EHR incentive program is still in the early stages, but evidence is mounting that, overall, the program is a positive force for change in the U.S. health care system.

As you are well aware, implementing regulations always represent a compromise between a multitude of stakeholders. The Meaningful Use regulations are no different, and the exchange requirements contained in Stage 2 represent a compromise between setting much higher expectations, as advocated by consumers and employers, and the slower approach advocated by many providers and others in the health care industry. Indeed, the report points out the tension faced by Congress and regulators: how to effectively use taxpayer dollars to push for the adoption of health IT to improve the health care system while not placing undue burdens on providers.

It is precisely this tension that yielded the balanced approach contained in both stages of Meaningful Use. The Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Health IT (ONC) developed this approach deliberately, based on recommendations of the Health IT Policy Committee, a federal advisory body created by Congress in HITECH and consisting of representatives of patient groups, providers, health plans and technology vendors. Most of the members of this Committee are appointed by the Government Accountability Office (GAO) to specific slots designated by Congress; four are appointed by Members of Congress, and three are appointed by HHS.

We mention this to make clear that the original Meaningful Use criteria were developed by consensus of this multi-stakeholder body, with an eye toward achieving this balance. It was the Policy Committee, too, that first recognized

² 77 Fed. Reg. 53968 (Sept. 4, 2012); 77 Fed. Reg. 54163 (Sept. 4, 2012).

that achieving truly "meaningful" use of health IT to transform health care would require a staged approach. This first stage involved providers adopting electronic systems and populating them with patient data, and at least using that data in their practices and institutions to improve care and report on public health measures. The second and third stages – which we are just beginning – build on this foundation with increased expectations with respect to use of health IT to fully engage patients in their care, to better coordinate patient care across settings, and to begin achieving changes in outcomes, both for individuals and for populations.

For the first two stages of Meaningful Use, the Policy Committee's recommendations were turned by ONC into proposed program criteria, which were then subject to public comment. There was substantial and significant public interest in these regulations and hundreds of comments were submitted, resulting in a number of changes to the proposed criteria in direct response to concerns and issues raised by stakeholders. Similarly, for Stage 3, the Policy Committee is beginning by examining the experience of providers under the HITECH program to date – which the report acknowledges is the right first step – and is looking to consolidate measures and requirements specifically to reduce provider burden while also ensuring that the Meaningful Use program achieves its main objectives. The proposed criteria released last year are just that – proposals, and merely a starting point for the development of a draft Stage 3 rule, which itself will be subject to public comment.

B. Voluntary Nature of Meaningful Use

It is important to consider that the HITECH program is not a mandate – it is voluntary. Entities who were early adopters, or who seek to advance their adoption and use of health IT more rapidly than required by Meaningful Use, are free to do so (and may be compelled to move forward with more robust use of health IT in response to payment reform initiatives). The Medicare penalties essentially establish a "play or pay" structure that still gives provides the option of assessing whether participation is a good business decision for them.

In fact, as the incentive program was just developing in 2009, there was speculation that the penalties may actually be too low, providing too little incentive for hospitals and physician groups to participate in the Meaningful Use program. Studies showed that a solid third of providers questioned were unaware of the financial penalties to which non-adopters would be subject, and that the majority of those would still not be motivated to adopt an EHR system, even in light of the penalties.³ Fortunately, participation rates have been quite

³ See, e.g., Merril, Molly. "Survey: Docs show little concern for meaningful use penalties," Healthcare IT News, *available at*: <http://www.healthcareitnews.com/news/survey-docs-show-little-concern-meaningful-use-penalties>.

high – the opposite of what was initially expected.⁴

C. A “Pause” is Not the Answer

As an organization that represents patients and consumers, we believe strongly that the very last thing we should be doing at this stage is slowing down, or “hitting pause.” Providers do not need more time to merely *adopt* technology – the deficiencies of our health care system demand that we reward actual use of EHRs to improve care. The report is correct that achieving interoperability and health information exchange sooner rather than later is of utmost importance. Pausing the incentive program, which has exceeded expectations with respect to the number of participating providers and the measures they have been able to achieve – would not only be counterproductive to achieving these goals, but would arguably constitute misspending of taxpayer dollars.

The Office of the National Coordinator for Health IT recently released a request for information asking the public for input regarding how to promote interoperability and advance the exchange of health information, taking full advantage of current health reform initiatives, payment and incentive programs, and consumer engagement. CDT was one of numerous stakeholders that submitted detailed proposals and ideas for how best to do this in a way that benefits all.⁵ The public comments submitted could be quite useful in thinking through strategies to more effectively promote interoperability and exchange.

II. Oversight

Oversight of Meaningful Use is a critical issue raised in the report. The attestation approach, which includes random audits, has its deficiencies – but given the circumstances, the Health IT Policy Committee believed it was the best way to ensure providers were reimbursed quickly for their substantial investments up front, without requiring them to first affirmatively demonstrate that they had met the criteria.

We certainly share your commitment to minimizing potential waste of taxpayer dollars and would support Congress dedicating more resources to the audit program, to help ensure that incentives paid out for meaningful use are

⁴ See, e.g., Office of the National Coordinator for Health IT Data Brief. “Physician Adoption of Electronic Health Record Technology to Meet Meaningful Use Objectives: 2009-2012,” available at: <http://www.healthit.gov/sites/default/files/onc-data-brief-7-december-2012.pdf>.

⁵ CDT’s response to the RFI is available at <https://www.cdt.org/letter/interoperability-request-information>; CPeH’s letter is available at: http://www.nationalpartnership.org/site/DocServer/CBC-CPeH_Comments_on_Interoperability_RFI.pdf.

appropriate. We share also your concern related to EHR vendors using contracts to block or require increased resources for the exchange of data from competitors. We would support barring such vendors from program certification if they were found to be engaging in this type of anti-competitive behavior.

III. Patient Privacy and Security

We commend your attention to the issue of patient privacy, and we share your commitment to ensure that certified EHR technology is as secure as possible. We note that the reports cited do not address privacy and security issues related to certified EHRs in provider settings.

However, we agree that more can and should be done to protect the privacy of identifiable patient health information. Although certified EHRs are required to have basic security features, providers need to actually use these functionalities in order to reduce the risk of a privacy violation. Unfortunately, we know from survey data that health care providers have not paid sufficient attention to information security, even though all are required to comply with the Health Insurance Portability and Accountability Act (HIPAA) Security Rule. We urge your support for strong HIPAA enforcement by the Office for Civil Rights (OCR), as well as the issuance of more frequent and detailed guidance to providers regarding how to comply with their HIPAA requirements.

We also urge you to review the privacy and security policy recommendations issued by the Health IT Policy Committee, as developed by its subgroup, the Privacy and Security “Tiger Team.”⁶ We chair this Tiger Team. Like the full Health IT Policy Committee, it is multi-stakeholder, and we have worked tirelessly over the past four years to consider the myriad privacy issues related to health IT broadly and Meaningful Use in particular. Our workgroup, which includes providers, in addition to vendors and consumer representatives, has met at least twice a month since 2009, held numerous hearings and issued dozens of recommendations endorsed by the full Policy Committee and forwarded to HHS for its consideration.

Our recommendations have led, among other things, to the increasingly robust privacy and security criteria in Meaningful Use; guidance to state health information exchanges on the issue of patient consent; and best practices for identity management of EHR users. ONC is also considering issues of patient identity matching, on which the Tiger Team has worked extensively. Although there is always the potential to do more to protect patient privacy and ensure data security, we have worked hard to strike exactly the balance recommended

⁶ <http://www.healthit.gov/policy-researchers-implementers/federal-advisory-committees-facas/privacy-security-tiger-team>.

in the report: holding providers accountable for complying with their legal requirements, incentivizing additional privacy and security measures, but also recognizing that information exchange in a care setting requires data mobility and reasonable workflows that do not overly burden providers.

Conclusion

Again, we thank you for your attention to these important issues and your commitment to protecting and realizing the value of this unprecedented investment in health IT. We appreciate the opportunity to comment and look forward to continued discussion. Please do not hesitate to let us know if we can be of further assistance.

Sincerely,



Deven McGraw, Director, Health Privacy Project



Alice Leiter
Policy Counsel, Health Privacy Project