



April 22, 2013

Submitted electronically

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Attention: *Interoperability RFI*
Hubert H. Humphrey Building
Suite 729D
200 Independence Ave., SW
Washington, D.C. 20201

Dear Secretary Sebelius:

Thank you for the opportunity to comment on this important request for information. We are committed to advancing the use and exchange of electronic health information through interoperable systems in secure, privacy-protective ways and appreciate the shared goals of your Department.

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 five 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”).

In response to HHS' request for information, we offer comments in the areas of:

1. Patient Access to Information;
2. Blue Button Plus;
3. Interoperability; and
4. HIPAA and OCR.

We reference the relevant question(s) asked in the RFI at the top of each of our comment sections.

I. Patient Access to Information

What CMS and ONC policies and programs would most impact patient access and use of their electronic health information in the management of their care and health? How should CMS and ONC develop, refine and/or implement policies and program[s] to maximize beneficiary access to their health information and engagement in their care?

The inclusion of the “view/download/transmit” (V/D/T) criteria in the final Stage 2 Meaningful Use rule has had the most significant impact to date on encouraging and enabling patient access to and use of their electronic health information. From 2011 to 2012, growth in physician adoption of electronic health record (EHR) technology to engage patients and families in their health care was especially strong. Over half of physicians capable of meeting select Meaningful Use criteria adopted computerized capabilities to provide patients with clinical summaries and electronic copies of their health in 2012. Further, that same pool of physicians' capability to exchange secure messages with patients increased by 40 percent from 2011 to 2012.¹

It is CDT's hope that this criterion will be advanced in Stage 3, not only because of the increased connectivity and patient engagement it will allow on its own, but because of the message such prioritization sends the industry. As discussed in greater detail below, requirements in Meaningful Use have far-reaching implications not only for EHR vendors, but also for software application developers both big and small. They are a catalyst for a fundamental and necessary redesign of the health care system and serve as a springboard for continued innovation. If HHS wants to send the message that it is committed to making easy, secure patient access to health data a reality, it must boldly advance V/D/T and related requirements, not just in Meaningful Use but also in other HHS programs and regulations.

¹ ONC analysis of 2009-1012 National Electronic Health Records Surveys, available at: <http://www.healthit.gov/sites/default/files/onc-data-brief-7-december-2012.pdf>.

The 2011 Clinical Laboratory Improvement Amendments (CLIA) regulation is a good example of this synergy of advancement. CDT wrote in support of the regulation's requirement that patients be given direct access to their laboratory results, and we urge its finalization as soon as possible.² A fundamental part of increasing patients' engagement in their health involves access to information, which gives them the opportunity – if they so choose – to be active participants in their own care.

This direct-access approach is found in Meaningful Use and we hope soon in CLIA, as well as in the Health Insurance Portability and Accountability Act (HIPAA). Aligning all of HHS' subagencies in pursuit of shared goals is paramount to their success, and the Department should be proactive in identifying and then swiftly acting on opportunities to do so.

We note that in CDT's comments to the request for information regarding proposed criteria for Meaningful Use Stage 3 on the topic of advancing the V/D/T criteria, we discussed the need for ONC to provide guidance to patients with respect to the benefits and risks of the use of such capabilities.³ Increased access to health information is not without privacy and security implications, and we yet again endorse the recommendations regarding transparency developed by the Health IT Policy Committee's (HITPC) Privacy & Security Tiger Team.⁴

We understand why these recommendations on transparency were not incorporated as certification criteria for Certified EHR Technology (CEHRT), but we urge HHS to promptly pursue other approaches (such as working with EHR vendors to seek voluntary adoption of lightweight notices to patients using V/D/T and outreach to patients using some of the same tools used to educate the public generally about EHRs and health IT) to help ensure patients using V/D/T understand both the risks and benefits.

II. Blue Button Plus

To what extent do current CMS payment policies encourage or impede electronic information exchange across health care provider organizations, particularly

² Harley Geiger, "Under Proposed Rule, Patients Will Receive Clinical Test Results Directly", Center for Democracy & Technology, (September 13, 2011), available at: <https://www.cdt.org/blogs/harley-geiger/139under-proposed-rule-patients-will-receive-clinical-test-results-directly>.

³ "Public Comment on Stage 3 Definition of Meaningful Use", Center for Democracy & Technology, (January 14, 2013), available at: https://www.cdt.org/files/pdfs/20140114_meaningful_use_3_comments.pdf.

⁴ The full set of relevant Tiger Team recommendations is available at <http://www.healthit.gov/policy-researchers-implementers/health-it-policy-committee-recommendations-national-coordinator-heal> (August 2011).

those that may be market competitors? Furthermore, what CMS and ONC programs and policies would specifically address the cultural and economic disincentives for HIE that result in “data lock-in” or restricting consumer and provider choice in services and providers? Are there specific ways in which providers and vendors could be encouraged to send, receive, and integrate health information from other treating providers outside of their practice or system?

How could the EHR Incentives Program advance provider directories that would support exchange of health information between Eligible Professionals participating in the program? For example, could the attestation process capture provider identifiers that could be accessed to enable exchange among participating EPs?

What CMS and ONC policies and programs would most impact patient access and use of their electronic health information in the management of their care and health? How should CMS and ONC develop, refine and/or implement policies and program[s] to maximize beneficiary access to their health information and engagement in their care?

Three of the main barriers to the electronic exchange of health information are (1) making data available for uses, both clinical and personal; (2) getting patients and providers to drive exchange by actually using exchange tools; and (3) resolving uncertainties about legal liability for exchange, which too frequently cause providers to decline exchange in order to minimize risk. The first two challenges arise from too few incentives for data holders to implement mechanisms that make data easily available, as well as a fundamental coordination problem due to thousands of data holders and potentially tens of thousands of software applications that want to communicate securely with one another. (The third challenge is addressed in the next section.)

The V/D/T incentives provided through Meaningful Use, discussed above, are a very good start toward combating the first two barriers. Much time and effort has been spent (and continues to be spent) in preparing to implement more robust health information exchange, both between providers as well as between providers and patients, using the DIRECT standard. HHS should continue its work with the DIRECT stakeholder community to ensure that implementation is as seamless as possible. Easy implementation for consumers and patients, for whom we have fewer direct channels for outreach, is of particular importance.

While the emphasis on DIRECT and eliminating both policy and technology obstacles to exchange is an important first step, and essential for Stage 2, HHS should be careful not to “lock in” a particular technological approach to exchange that in time will likely be superseded by more flexible and efficient exchange

models.

It is critical that the Meaningful Use program continue to be a tool that supports innovation and promotes interoperable data exchange while remaining agnostic with respect to the particular technical model of exchange. In future stages of Meaningful Use and in considering how to leverage other HHS programs to provide incentives for sharing patient data, we urge HHS to focus more on building an infrastructure or platforms for HIE, facilitating an ecosystem that equally supports a variety of models of exchange, both “push” — e.g., DIRECT — and “pull.”

We are pleased that the certification criteria for Stage 2 allow for optional certification of “pull” transmission using RESTful access points,⁵ and we further urge ONC to pilot implementation of RESTful exchange, particularly with patients, in order to test promising exchange models while at the same time implementing V/D/T using DIRECT in Stage 2 as planned. The Blue Button Plus initiative also is moving in the direction of encouraging innovation by putting forth several proposals that allow discovering EHR-based resources on a provider's web site and mechanisms for applications to register with providers, or to enable the user to authorize the application to upload and analyze his or her EHR data.

We support the work of the Blue Button Plus initiative in further developing standards and policies for “pull” models of the Blue Button that ultimately can be added to the CEHRT criteria for V/D/T. Achieving greater connectivity, with technology approaches that support provider workflows while meeting the needs and expectations of patients, should continue to be the overarching goal of this effort.

III. Interoperability and Exchange

On the issues of developing a wider array of more robust standards, promoting interoperability and increasing participation in health information exchange, we support the joint recommendations of the Consumer Partnership for eHealth (CPeH) and the Campaign for Better Care (CBC), whose letter we have joined as a signatory.

⁵ 45 CFR 170.314(b)(2) requires the eligible provider to 1) create a Consolidated-CDA with data specified for MU and 2) enable a user to transmit via: DIRECT (required) or via other optional “pull” mechanisms.

IV. Employing HIPAA and OCR to Facilitate Secure Exchange

Which of the following programs are having the greatest impact on encouraging electronic health information exchange: Hospital readmission payment adjustments, value-based purchasing, bundled payments, ACOs, Medicare Advantage, Medicare and Medicaid EHR Incentive Programs (Meaningful Use), or medical/health homes? Are there any aspects of the design or implementation of these programs that are limiting their potential impact on encouraging care coordination and quality improvement across settings of care and among organizations that are market competitors?

What CMS and ONC policies and programs would most impact patient access and use of their electronic health information in the management of their care and health? How should CMS and ONC develop, refine and/or implement policies and program[s] to maximize beneficiary access to their health information and engagement in their care?

HIPAA and its enforcement body (the Office for Civil Rights, or OCR) are too frequently left out of discussions about ways to promote increased interoperability, information exchange and patient engagement. We were disappointed that OCR was not specifically mentioned in the RFI as a sub-agency within HHS with the potential to advance critical health information exchange initiatives.

This is more than a mere oversight. HIPAA is the original guarantor of a patient's right to his or her own health information,⁶ and failure to align HIPAA's policies with other initiatives to promote patient access to information undermines the Department's avowed support of patient access initiatives. In addition, the HIPAA Privacy and Security rules are critical policy tools for advancing conditions of trust for nationwide health information exchange; however, these tools are not being utilized to their full potential.

Too often HIPAA is cited as an excuse for why exchange is not possible. This view of HIPAA as a barrier to exchange, rather than a facilitator, is clearly misconceived, but fears of legal liability and subsequent HIPAA penalties are nonetheless real, with real consequences. As a result, the Administration must be proactive, nimble and fast in addressing them.

OCR previously has issued guidance about compliance with HIPAA, but much more abundant and specific guidance is needed in order to clarify expectations and reduce uncertainties for providers, many of whom are exchanging health information digitally across networks for the first time. Providers also need clarity on how the HIPAA rules apply to the exchange of clinical information with patients, such as through the Stage 2 V/D/T criterion.

⁶ 45 C.F.R. § 164.524.

Such guidance should provide concrete examples of activities that are (and are not) considered to be in compliance with the rules, at each and every individual step of the exchange process. For example, what reasonable steps should providers take to ascertain the digital identity of a provider at the other end of an exchange transaction? What reasonable steps should providers take to determine whether or not a provider requesting a patient's records is authorized to receive those records under HIPAA? OCR should promptly address critical questions in time to enable providers to meet the exchange and patient engagement requirements of Meaningful Use.

As noted above, the patient access provisions of HIPAA need substantial strengthening. The January final rule implementing HIPAA revisions made in the 2009 HITECH law expanded patient access in a number of ways, including requiring provision of an electronic record copy of a medical record if requested. But to the dismay of CDT and other privacy and consumer advocates, the timeframe for access was not meaningfully altered. Opportunities to revise HIPAA do not frequently arise, and it is disappointing that, at least with respect to patient engagement, only the bare minimum was accomplished during this most recent one.

If the Privacy Rule had been amended to instead align with Meaningful Use Stage 2 on this front, the timing would be advanced significantly: under Meaningful Use, eligible professionals must provide patients with the ability to view online, download and transmit their health information within four business days of the information being available to the provider.⁷ This change would have had a significant impact on the potential for patient engagement.

OCR has recently become much more stringent in both its policing and enforcement of the regulations, from collecting monetary settlements for alleged HIPAA violations from an increasing number of providers to performing compliance audits of both covered entities and business associates. This increased commitment to enforcement is another way in which OCR, through HIPAA, can help advance interoperability, exchange and patient engagement. These settlements and the audits will yield important information about the most common HIPAA regulatory provisions that are not being adequately addressed by HIPAA-covered providers or their business associates, providing a clear opportunity for OCR to address gaps in compliance and highlighting provisions that could be subject to attestation in the third stage of Meaningful Use. At the same time, this increased enforcement activity has contributed to increased liability concerns on the part of providers, making it all the more critical that the uptick in enforcement be matched by an increase in comprehensive guidance for providers and the public.

⁷ 77 Fed. Reg. 53968-54162 at 54150 (Sept. 4, 2012).

As we explore ways to increase information exchange and drive advancement in interoperability, we should not ignore the major, foundational health privacy law and its enormously effective enforcement body.

V. Conclusion

We thank HHS for this opportunity to submit comments. Please do not hesitate to contact us if we can be of any assistance.

Respectfully submitted on behalf of the Health Privacy Project,

A handwritten signature in cursive script that reads "Deven McGraw".

Deven McGraw
Director, Health Privacy Project CDT