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27 November 2017

By Electronic Mail

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Office of the National Coordinator for Healthcare Information Technology
U.S. Department of Health and Human Services
330 C Street SW
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RE: HRBA's comments following our 24 October 2017 telephone call on Cures Act implementation

Dear Dr. Rucker:

We appreciate your and your staff's taking time on October 24 to discuss with me and my HRBA colleagues, Bill Yasnoff, Richard Marks, and Lisa Nelson, the comments HRBA filed on August 24. Those comments, in response to ONC's request, addressed the statutory and systems requirements for ONC's implementation of the 21st Century Cures Act. We are following up on that telephone conference.

**The Cures Act Framework Demands New, Comprehensive Data Exchange Capabilities**

We at HRBA believe ONC's goal should be to render healthcare data liquid, making it easy to move, routinely, in a comprehensive standard format, without prior discussion or other arrangements, securely, and when and as requested by authorized users. Only that level of ease of use among all electronic health record (EHR) systems will enable marketplace solutions for health information exchange – solutions that can earn wide acceptance among users, including consumers, and so prevail in the market.

The Cures Act sets a very high regulatory standard for ONC to meet regarding liquidity of health information. Before we discuss HRBA's reactions to our October 24 call, we want briefly to summarize the multi-faceted, mandatory Cures Act standard as we read it. Doing so sets a

baseline for the analysis that follows. Then we want to compare ONC's preliminary thoughts about regulatory options (as we understand them) to what the Cures Act requires.

Summarizing HRBA's written comments: The Cures Act directs ONC to create significant, powerful new benefits for "users" of health information technology. Cures Act "users" include consumers and consumer groups in addition to traditional EHR system users such as hospitals, physician offices, and payors.

For practical and legal purposes, consumers are now among those who will use, and benefit from their use of, EHR systems installed in hospitals and physician offices. The Cures Act thus confers specific benefits on patients and other consumers. Congress's intent is reflected in design specifications and policy goals stated specifically in the Cures Act. It is that consumers be able, with ease, to use EHR systems to manage their health and healthcare when interacting with the nation's healthcare system.

To meet Cures Act requirements when installed in hospitals and physician offices, EHR systems must, on users' request, be able to export complete information sets as part of access to, or exchange of, health information. ONC regulations must forbid implementing EHR and other health information technology in nonstandard ways that are likely to substantially increase the complexity or burden of access to, or exchange of, health information. Among other things, these capabilities include transmitting to and receiving from clinical data registries. This capability will promote innovation and expansion of specialty and disease-specific health information by making its exchange accessible, inexpensive, and easy to use.

The pressure for regulatory action is great because data exchanges contemplated by the Cures Act go far beyond capabilities of existing EHR systems. Users must be able to securely exchange and use digital health data "without special effort." This Cures Act directive distributes over all aspects of ONC's policy development. That is, it must be pervasive. It is an unprecedented systems design requirement for health data systems. It applies to the vast installed base of EHR systems that presently cannot exchange complete health records because they lack standardized outbound and inbound interfaces mapped to their various, proprietary system formats.

For EHR systems to meet these criteria, ONC cannot avoid adopting national exchange standards to enable exchange in "computable" formats. Inevitably, exchanges among a variety of users, using a variety of proprietary EHR systems, must result in mapped inputs in order to achieve the Cures Act's design specifications and policy goals. Only in that way can clinicians at receiving hospitals, without special effort, find particular received data elements where they should normally be stored in their institutional EHR systems. To make mapped inputs possible for receiving EHRs, the outputs of sending EHRs must be mapped according to the exchange standard, too. It cannot be otherwise. It is an engineering imperative imposed by the Cures Act.

The policies ONC adopts must ensure that this set of data exchange capabilities become available within short, mandated time periods. The statute further directs ONC to accomplish this goal by giving deference to standards published by standards development organizations and voluntary consensus-based standards bodies.

While Cures Act entitlements accrue to hospitals and physicians because of the EHR systems they use, consumer rights under the statute deserve special attention because they are new. If ONC's policies and implementing regulations do not fully implement Cures Act data exchange rights for consumers, one can predict at least three consequences: further postponement of consumer sovereignty and control over their health care; political demands for fuller Cures Act implementation, in Congress and in the courts; and increased litigation risk as consumer groups seek enforcement in the federal courts of their panoply of new Cures Act rights.

Because consumers are among the stated, intended beneficiaries of the Cures Act's data exchange provisions, consumer groups (such as disease-specific groups) will have standing in federal court. Standing will enable them to insist that ONC's regulations effect the Cures Act's data exchange provisions comprehensively.

The fortunate circumstance is that existing, private sector data exchange standards exist. ONC is of course aware of these standards (Direct for transport and identity proofing and Consolidated Clinical Document Architecture (C-CDA) for content). These industry standards are sufficiently developed so that they are robust now, as well as being amenable to expansion and open to continued technological development. They are published by recognized, voluntary, consensus-based standards bodies. They can be engineered by EHR system vendors into existing EHR systems. Considering the systems engineering capabilities these vendors possess, present circumstances offer ONC a straightforward path to adopting regulations consistent with the Cures Act's vision.

**APIs in Their Present State of Development Cannot Meet Cures Act Requirements**

In our telephone meeting on 24 October 2017, the HRBA participants learned that ONC is considering attempting to satisfy the Cures Act's mandates by relying heavily on Application Programming Interfaces (APIs). We believe that APIs, even those instantiated using Fast Healthcare Interoperability Resources (FHIR) specifications as they currently exist, do not and cannot satisfy Cures Act specifications within the statutory time frame.

This is true as well for applications using SMART (Substitutable Medical Applications, Reusable Technologies) on FHIR. FHIR and SMART on FHIR will not timely meet statutory goals nor solve the current lack of nationwide interoperability for these reasons:

- FHIR is an emerging standard and it will take years of FHIR development to unleash all the data elements currently being held hostage in EHRs. The Health Insurance Portability and Accountability Act (HIPAA), the HITECH Act as amended by the Cures Act, and the Cures Act itself together state that patients are entitled to all their electronic health record data now – as "complete" records – not just the handful of data elements EHR vendors may choose to release via FHIR APIs.

- FHIR will never meet the statutory requirements and tight deadlines of the Cures Act because the standard is not in widespread use now. It is too early in its lifespan. FHIR may be in our future, but it is not ready now.

- SMART on FHIR is not a health information exchange methodology or technology. It is a data access, or information access, methodology. SMART on FHIR is largely used for internal organizational APIs written against a narrow set of (FHIR) resources within a given health system. It does not address inter-organizational exchange or health system-to-consumer exchange.

- Currently, FHIR has too much optionality, and resources are underspecified. Today, this leads to inconsistent implementations of existing profiles. The degree of uniformity needed for consistent, reliable health data exchange under the Cures Act is well into the future.

- FHIR as it stands today is missing crucial infrastructure components: patient identity proofing, provider and organization directory services, patient record locator services, and a trust framework within which to authenticate and authorize relying parties at national scale.

- SMART on FHIR in APIs would, absent substantial regulation and burdensome HHS enforcement, allow EHR vendors to charge exorbitant interface fees, which are enablers of information blocking and hence prohibited under the Cures Act.

- FHIR APIs are today vulnerable to security risks. FHIR lacks both the industry consensus necessary for a common trust agreement and business rules for a wide variety of transactions that must be standardized in any national trusted exchange framework under the Cures Act.

- At this point, FHIR does not traffic in documents such as History and Physicals, Operative Notes, Consultation Notes, and Discharge Summaries. These are examples of documents that provide crucial historical context for informing current care.

- SMART on FHIR does not address all the healthcare entities that are not on EHRs, such as skilled nursing, long-term care, home health, and public health facilities.

- ONC does not need to pick a health data exchange standard – the private sector already has: the Direct protocol for transport (1.6 million end-user Direct addresses at more than 100,000 healthcare organizations exchanging 200 million messages per year) and C-CDA documents for content (the 12 C-CDA document formats cover all significant data types in the typical EHR, and new C-CDA document templates are under development and will continue to be for purposes of essentially unlimited expansion over time).

- ONC could fund projects to extend and align the value sets used by C-CDA and FHIR. Doing so would promote easy conversion between the C-CDAs used today, the expansion of those sets, and the future use of FHIR APIs. It would help ensure that EHRs and consumer health records can achieve ever-greater levels of semantic interoperability.

**ONC Can Implement the Cures Act Comprehensively Through Regulation By Adopting Existing Private Sector Standards for Health Data Exchange**

Therefore, we strongly recommend that ONC defer to private sector standards already in widespread use: the Direct protocol and C-CDA. They support a wide array of good things (including further development of FHIR APIs), don't do bad things, and would allow a variety of current health information exchange efforts and comprehensive, longitudinal consumer health records to flourish within a short time frame.

You know of HRBA's strong advocacy for health information exchange via secure, private-sector repositories to hold consumer-owned lifetime health records (health record banks). We believe that making health data liquid is the precursor to the private sector's offering consumers lifetime health records they own and control. Yet the validity of those expectations need not even be considered to justify the recommendations we suggest as ONC contemplates the most effective path to implementing the Cures Act.

Rather, the engineering imperatives one derives from the Cures Act (and HITECH as amended by the Cures Act) are all that are necessary to justify the regulatory recommendations we offer here. We agree with you that government should not dictate private sector solutions. That is true even after health data become liquid and their exchange can be accomplished without special effort. Enabling the private sector to work its magic and solve the interoperability conundrum are what these suggestions are all about.

- Changes in the insurance marketplace certainly will lead informed consumers – those armed with easy access to their longitudinal health records – to shop for healthcare services. They will compare and switch providers as circumstance and their judgment dictates. Patient safety demands that their next provider be informed through access to their complete, formatted health records at the time of their introductory visit.

- As consumers see new providers who must quickly and with ease become informed about new patients' medical histories, consumers who have collected their prior lab and imaging studies will save the cost and risk of new, often unnecessary procedures.

- Some remarkably capable firms are applying natural language processing and machine learning to unstructured data. Technical capabilities in this arena will explode as data routinely flow out of EHRs upon request, and under the control, of authorized users.

- Technology innovators have created hundreds of thousands of mobile health apps already. Imagine the possibilities if, in addition to fitness tracker data, they had access to the collected health records, images, and genomics of the consenting consumer. We can envision the day when consumers will receive competent advice via their mobile phones while trying to decide whether to manage their symptoms at home, wait a few days for an office visit, seek care at an urgent care center, or go to an emergency department.

- Consumers with their full healthcare information would be able to more effectively research their conditions on the internet and seek the most appropriate, most convenient, and most affordable professional help and second opinions. Until then, and without easy access to their complete longitudinal records, consumers would, by and large, be incapable of participating in the healthcare marketplace of the future. ONC can begin to

change that situation within a year, consistent with Cures Act time frames. ONC can accelerate changes in the healthcare market, at long last, to offer consumers sovereignty over their health records.

- Healthcare costs cannot come down without market forces, and market forces will not prevail effectively without price transparency. Willing patients are not enough; they must be armed with their medical data. Only then can innovators can be sure that patients receive the appropriate diagnostic and therapeutic interventions based on their documented conditions.

Healthcare costs are out of control, access to health data is inadequate, and consumers are insufficiently engaged in their care; the need for healthcare innovation has never been greater. Enabling consumers to have automatic access to all their medical data, continuously updated, will unleash private sector innovation.

The industry is poised to develop new care models and services, rewarding consumers and entrepreneurs alike. Inadequate federal policy on implementing health data legislation and health information exchange has been an insurmountable obstacle for most of two decades. By removing these obstacles to health information liquidity – by designating Direct for transport and C-CDA for standard formatting in a nationwide health data exchange standard – ONC can accelerate the launch of a new ecosystem of empowered healthcare consumers.

We look forward to your questions. Thank you for taking time to discuss these challenges with us.

Yours truly,

Richard Gibson

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