

Health Record Banking Alliance
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Via Email: micky.tripathi@hhs.gov

Dr. Micky Tripathi
National Coordinator for Health Information Technology
Department of Health and Human Services
Washington, DC

Dear Dr. Tripathi:

We haven't spoken in close to two decades, so I want to say hello, congratulate you on becoming National Coordinator, and introduce you to the work of HRBA, the Health Record Banking Alliance. We look forward to working with you and your colleagues at ONC in coming months and years.

In 2015 and 2016, HRBA met with staff of the House Energy and Commerce Committee and the Senate HELP Committee. Our recommendations addressed engineering, systems design, and policy options in advance of the 21st Century Cures Act. We were gratified to see congruence between our discussions with committee staffs and the design specifications for data exchange that emerged in the Cures Act.

HRBA also submitted extensive comments to ONC in the Interoperability Rule Making. Our purpose was to assure faithful adherence to the detailed systems requirements in the Cures Act. HRBA had concerns regarding ONC's initial rule proposals, and commented on them critically and specifically. When the final Interoperability Rule was released, we again were gratified to see substantial congruence between it and HRBA's statutory interpretation of the Cures Act's systems design for digital health data exchange. I refer specifically to what is, essentially, *a national digital health data exchange standard* in 45 CFR Sections 170.213, .215, .299, and .315. The "*Exchange Standard*" operates at the core of the Interoperability Rule.

Immediate Regulatory Issue: "Broadcast Query"

ONC is working now on details in implementing the Interoperability Rule. HRBA has a principal concern about this phase of implementation. If ONC requires "broadcast query" in the Common Agreement, that would be an insurmountable obstacle to TEFCA's success, and to success of the Exchange Standard.

By "broadcast query" we mean the theoretical model for compiling a patient's data in "real time" at the point of care. In theory, a treating clinician would broadcast a message to *all* Electronic Health Record (EHR) systems nationally. The message would trigger *all* EHRs nationwide to search immediately for the particular patient's medical records. Any EHR that identified that patient *with certainty* would be required immediately to send the patient's records by return message to the requesting clinician. All such records would be assembled into an up-to-the-moment aggregate medical record for the treating clinician's use.

This theoretical model persists in the lore of interoperability, but it has been discredited and proven wholly unworkable in practice. "Broadcast query" messages would overload networks. Security, privacy, and matching problems in identifying the patient and the patient's records are insurmountable. Liability dangers flowing from these defects are significant to the point of operational paralysis. These systems design defects are documented (for example, in the Santa Barbara project and in evaluation of ONC's 2007 NHIN Prototype Architecture Contracts) and widely recognized.

In earlier comments to ONC regarding TEFCA, HRBA stated that faithful implementation of the Cures Act *requires* dropping "broadcast query" from the Common Agreement. Otherwise, attempting to achieve nationwide health data interoperability will be a futile exercise. This perverse outcome would be particularly

galling because the Exchange Standard makes “broadcast query” wholly unnecessary for efficient, reliable, secure, successful nationwide health data exchange.

This is so because the Exchange Standard enables point-to-point health data interchange on the Internet. For example, a consumer with a secure account in a health data bank (HDB) will receive encounter reports from various doctors, hospitals, and other care providers directly and securely. Similarly, a consumer with a compiled, lifetime PHR (Personal Health Record) on an HDB platform will send all or parts of the record directly and securely to doctors, hospitals, and other providers using the Exchange Standard. Because the Interoperability Rule obviates any need for “broadcast query,” and because “broadcast query” is disabling to the nationwide system, making “broadcast query” capability mandatory in the Common Agreement would violate the Cures Act’s systems design specifications.

Longer Range Policy Goals

In comments HRBA consistently advocates for regulatory policies to expedite emergence of Health Data Banks as a major new industrial sector, a new structural layer, in U.S. healthcare. HDBs are secure, multi-service health data platforms serving as patients’ trusted agents. We anticipate HDBs will be developed by a variety of private, public, and non-profit sector enterprises. This will be a direct result of embedding the Exchange Standard as core functionality in the Interoperability Rule.

The routine data exchange the Rule enables in 45 CFR Sections 170.213, .215, .299, and .315 is *the* key to making HDBs commercially feasible. The Exchange Standard will allow patients, easily and routinely, to receive their medical encounter data from clinicians. They will aggregate, sort, update, and store all that data securely in HDB accounts the patients own and control. HDBs will offer PHRs with a problem-oriented structure and advanced analytics to turn data into information. Problem orientation on HDB platforms will improve usability and clinical functionality and reduce clinician burden. Using HDBs, patients can make all or selected parts of their PHR records available to clinicians in aid of examinations, diagnoses, and treatments – and, identified or de-identified, to medical researchers whose work they support.

For these reasons, helping make HDBs available to the public should be a central regulatory goal for ONC. HRBA’s two-page systems design overview for patient-centric data exchange using HDBs is attached.

Congress’ Role

We are writing to Representatives Diana DeGette and Fred Upton as they consider legislation for Cures Act 2.0. We explain how HDBs will transform data flows in U.S. healthcare; and we are asking Congress to consider specifying a regulatory framework for HDBs. The aim is to keep bad actors out of this new industrial sector, while allowing HDBs to innovate in services to consumers who open HDB accounts.

As noted above, problem-oriented PHRs operating on HDB platforms will use the Exchange Standard to communicate back and forth with EHR systems in doctors’ offices and hospitals. The design of a national regulatory framework for these new platforms, functions, and data flows is an opportunity to make care and medical research more efficient, faster, and cost-effective.

We at HRBA look forward to conferring with you and your colleagues at ONC on health data exchange. We would be pleased to discuss and answer questions you have about anything in this letter.

Sincerely yours,

Richard D. Marks
Richard D. Marks
Vice President
Health Record Banking Alliance

Attachments: HRBA Systems Overview and Schematic for Health Data Exchange