

Health Record Banking Alliance
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Via Electronic Mail to cures2@mail.house.gov

Hon. Diana DeGette
Hon. Fred Upton
Committee on Energy and Commerce
U.S. House of Representatives

Dear Representatives DeGette and Upton:

The Health Record Banking Alliance (<http://www.healthbanking.org/hrba-overview.html>) proposes engineering and policy recommendations to support private, public, and non-profit sector investment in, and development of, health data banks (HDBs). We hope you will consider incorporating these recommendations in Cures 2.0 legislation.

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. (A systems overview is attached.)

In the months before the Cures Act was passed at the end of 2016, HRBA met with your committee's staff and with the staff of the Senate Committee on Health, Education, Labor and Pensions. We were pleased to see a congruence between the Cures Act's engineering and systems design specifications for health data interchange and the engineering, systems design, and policy options we proposed to your staff.

As a result of Cures Act mandates, ONC's Interoperability Rule includes *a national digital health data exchange standard* in 45 CFR Sections 170.213, .215, .299, and .315. This is something HRBA long advocated. The data exchange standard becomes operational in December of 2023. Patients finally will be able – securely, easily, reliably – to gather digital encounter records from doctors and hospitals. Patients then will use HDB platforms to aggregate, structure, and store the compiled data in lifetime health records that the patients own, control, and use.

You may expect HDBs to emerge as a vital new structural layer in our country's healthcare system. HDBs will usher in new information flows and problem-oriented personal health record (PHR) technology with advanced analytical capabilities. *Problem-oriented analytics will turn compiled data into information.* That way the aggregated, "lifetime" records in HDBs will be far more useful to patients and clinicians than current fragmentary encounter data or disparate application programming interfaces (APIs). HDB platforms will ameliorate widespread burdens on physicians who today are overwhelmed by siloed electronic health record (EHR) systems. HDBs, centered on patients, will benefit clinicians, hospitals, medical researchers, employers, the health insurance industry, and all U.S. health care.

As we predicted in our letter to you of December 16, 2019 (attached):

HRBA members continue to explore and refine the engineering, security and privacy, business, statutory, and regulatory considerations necessary to expand patients' rights to compile and use their own medical records. In the name of protecting privacy, there will be unreasonable efforts to constrain consumer choice in selecting and using health record bank services; and there will be unreasonable efforts to constrain health record banks in the features and services they offer to consumers (including ways to connect patients with medical researchers). While baseline regulation of health record banks is necessary, Congress and the states will need to calibrate regulatory schemes so HRBs can innovate responsibly in offering a wide range of services to consumers.

HRBA looks forward to working with your committee as you craft a regulatory framework for HDBs to become a new structural layer in healthcare. Our overview of the systems design for this framework is attached.

Very truly yours,
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Attachments: HRBA Systems Design Overview and Schematic (2 pages)
HRBA letter of December 16, 2019 to Representatives DeGette and Upton