

Health Record Banking Alliance
P.O. Box 6580
Falls Church VA 22040
January 24, 2020

Via Electronic Mail to john.m.mulvaney@omb.eob.gov

Hon. John M. Mulvaney
Director, The Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

RE: Health Record Banking Alliance – Support for Proposed Rule for a National Digital Health Information Exchange Standard (Office of the National Coordinator for Health Information Technology, HHS)

Dear Director Mulvaney:

The Health Record Banking Alliance (www.healthbanking.org) strongly supports OMB's approving the Proposed Rule crafted by the Office of the National Coordinator (ONC) to implement the 21st Century Cures Act. We urge OMB to approve the Proposed Rule substantially as submitted by ONC.

A crucial element of the Proposed Rule is a *national digital health data exchange standard*. The *exchange standard* is contained in the updated certification criteria in the Proposed Rule for Electronic Medical Record (EMR) systems.

HRBA consistently advocated such a national digital health data exchange standard with Congress during drafting of the Cures Act. The exchange standard (and other ONC rules complementing it) will enable access to personal health data by individual citizens that has consistently been a high priority for this Administration.

Viewed practically, ONC's adoption of the exchange standard is *required* by the Cures Act, as HRBA demonstrated point-by-point in its comments to ONC during the rule making process leading to the Proposed Rule. Those comments are the attachment to this letter. They list and analyze the Cures Act's explicit engineering, policy, and legal requirements as Congress specified. (The legal reasoning in HRBA's comments demonstrates why threats by various interests to challenge the Proposed Rule in court will fail; the Proposed Rule is what the Cures Act demands.)

Establishing a national, digital health data exchange standard is essential both to implement the Cures Act and to enable a new category of health data institutions to emerge – health data banks that will hold consumers' health record accounts. Patients will use HIPAA's right of access to request and obtain copies of their medical records in a digital form that complies with the national digital exchange standard. Patients then will aggregate and access their lifetime health data as stored in secure personal health data accounts they own and control. They will use these accounts (often with assistance from professionals such as medical record social workers and certified health care consultants) to help manage their health and health care, and to support medical research they care about.

The national, digital health information exchange standard – essential to the operational core of the Proposed Rule – *will enable health data to be integrated around the patient*, rather than being held solely in often separate institutional record systems that are unable to communicate with each other. Integrating health data around the patient is inherently efficient. That integration is now possible in the U.S. with digital technology, but only if the exchange standard is promulgated nationally as ONC proposes. It is key to facilitating patient-centered healthcare markets.

Missing now in the U.S. health system are communications channels and complementary personal decision support software applications integrated around the patient. Health Record Banks using the evolving exchange standard will emerge to offer these new communications channels, and they in turn will enable new, more efficient, systemic health information flows. For the first time there will be alternatives for personal data access beyond the current tightly "siloes" systems of a few large electronic medical record vendors and integrated health care systems.

The historical inability of consumers to gain easy, routine, secure access to their lifetime medical data (an increasingly essential resource for health and well-being) is an anomaly in American society. Financial institutions, for example, have long adopted data standards that permit individuals to move their personal resources among institutions as they seek to obtain maximal value. In the same way, enabling individuals to incorporate key medical data securely into applications of their choosing will help health care consumers determine more appropriate and efficient ways to manage their health and health care. It will empower consumers and help transform a health care industry increasingly seen as information rich but knowledge poor.

Extensive evidence and experience show that limiting patients' access to their personal data does not improve the quality of medical care or protect patients from harm. Rather we perpetuate a national health care information technology infrastructure that is vulnerable to frequent damaging, costly, unauthorized access. We make it difficult for the frontline practitioner to obtain and use vital individual patient data at the point and time of care. The need to change from an institutionally dominant national health care information market to one that is individually focused is now widely acknowledged. ONC's Proposed Rule will begin the process by which just such a revolution in U.S. health care becomes an achievable goal.

Unfortunately, and despite the undoubted efficiency these groundbreaking rules will usher in, we are witnessing efforts to block or undercut them. Dominant interests in the patient data marketplace aim to limit consumer access to, and prevent expanding consumers' control of, their own health data. The argument is, essentially, that patients cannot be trusted with access to their own medical records, because some patients will misuse the information, or be confused (or alarmed) by it. A closely related fear is that patients will use unregulated application programming interfaces (APIs) or other unregulated computer resources to analyze their personal data.

All this is akin to arguing that consumers cannot be trusted to have access to their personal financial information.

These arguments are couched in fear and paternalism, outmoded in the digital age. These thinly disguised attempts to limit competition in the market for individual health data do not withstand scrutiny.

Ironically, this argument often emanates from dominant institutions and businesses that profit from continuous access to valuable, aggregated clinical data, which they exploit without patients' knowledge or realistic consent.

I recently assumed HRBA's presidency because, throughout my clinical, academic, and business careers, I have seen the damage that restricting access to personal health care data causes. Among other things, it consistently cripples adoption of new information technology applications that could support clinicians with refined knowledge of each patient's unique ability to respond to specific therapies. It hampers patients' ability to use their aggregated personal health data to support medical research of importance to them and their loved ones. And it makes the information flows in U.S. healthcare inefficient and unnecessarily delay-ridden and costly.

Medicine will increasingly encompass newly discovered, unique, personally based information such as genetic and biomarker profiles. All citizens, by right, must be able to access and manage these data to benefit themselves, their children, and future generations. We urge OMB to approve ONC's Proposed Rule substantially as submitted.

Very truly yours,
William A. Knaus
William A. Knaus, M.D., F.A.C.P.
President, Health Record Banking Alliance
wknaus@virginia.edu

Attachment:

Comments of the Health Record Banking Alliance on the Draft Trusted Exchange Framework and Common Agreement, submitted February 20, 2018 through exchangeframework@hhs.gov to the Office of the National Coordinator for Health Information Technology, Department of Health and Human Services (this document is also available at http://www.healthbanking.org/uploads/9/6/9/4/9694117/hrba_tefca_comments_20180220.pdf)

Copies Via Electronic Mail to:

Hon. Alex M. Azar II, Secretary, DHHS, Secretary@HHS.gov
Donald Rucker, MD, Office of the National Coordinator, DHHS, donald.rucker@hhs.gov