

**Comments of  
The Health Record Banking Alliance  
In response to**

**Department of Health and Human Services  
Centers for Medicare and Medicaid Services  
Reference File Code CMS-0058-NC**

Submitted December 6, 2022 via <http://www.regulations.gov>

The Health Record Banking Alliance (HRBA)<sup>1</sup> offers comments in response to the Centers for Medicare and Medicaid Services' request for information on a proposal to establish a National Directory of Healthcare Providers & Services (NDH) that could serve as a "centralized data hub" for healthcare provider, facility, and entity directory information nationwide.

HRBA supports this proposal because the NDH envisioned by CMS would be of transcendent utility to consumers who maintain longitudinal, lifetime health records in Health Data Banks (HDBs, also called Health Record Banks or HRBs). *(Please see the Appendix for a schematic overview of Health Data Banks.)*

For consumers, a CMS-maintained, vetted directory of digital endpoints for providers and provider-related services will offer consumers a new, essential level of trust in their ability to identify and contact providers reliably, securely, and directly. The impact of this trusted functionality will produce systemic benefits for enhanced health data exchange flows far beyond the directory domain itself.

While HDBs are not yet a force in the U.S. health industry, CMS should expect HDBs to begin to emerge after January 1, 2023. That is the day after the deadline by which initial versions of standardized FHIR-based application programming interfaces (APIs) required for certification under ONC's Interoperability Rule will become widely available to consumers.

As of that date, consumers will be able routinely, easily, reliably, securely, and affordably to obtain copies of their medical records from providers' disparate, and previously non-interoperable, electronic health record (EHR) systems. While the initial scope of exchangeable EHR data will be limited to the then-current version of the USCDI (United States Core for Data Interoperability), Consumers will nevertheless have the capacity to combine basic data from the various copies of their EHR records into normalized, problem-oriented lifetime health records stored in HRB accounts that the consumers own, maintain, and control. (See the Appendix for a diagrammatic depiction of these relationships.)

HRBA has suggested that a primary benefit of the FHIR-based health data exchange standard is the prospect of secure point-to-point digital data flows to replace the fax-based system that remains the de facto health data exchange standard today. Point-to-point data flows between consumers and providers, providers and other providers, consumers and payors, providers and payors, payors and other payors, and similar pathways will be an overriding

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<sup>1</sup> The Health Record Banking Alliance, P.O. Box 6580, Falls Church, Virginia 22040, is recognized as a business league by the Internal Revenue Service under Section 501(c)(6) of the Internal Revenue Code.

benefit of standardized FHIR-based interoperability. Seen in this systems design framework, the NDH will contribute trust, speed, and accuracy to data requests and other exchanges. As design of the NDH progresses in light of responses to this RFI, we urge CMS to give constant priority to how NDH directory services will contribute to the coming era of point-to-point (secure end-point to secure end-point) digital health data communications.

An NDH so designed also will be essential when Congress creates a national regulatory framework for the Health Data Bank sector. This overriding legislative need will soon become apparent. Uniform federal regulation of HDBs will be fundamental to protecting consumers and maintaining trust in the security and utility of FHIR-based, standardized digital health data exchange.

We are early in the multi-year process to implement ONC's new Interoperability Rule. However, even at this initial stage the Rule will put patients at the center of their care and in control of their health information. Integrating health records around each patient will usher in an enormous improvement in the efficiency of health information flows. This increased efficiency will benefit patients, clinicians, researchers, payors, and governmental health agencies at federal, state and local levels. It will offer consumers additional convenience when they shop for healthcare providers and for health insurance. It will fortify consumers' trust in new patterns of convenient health information exchange that the emerging HDB industry will bring to the U.S. health industry. For all these purposes, the NDH as proposed will be a welcome new source of trusted information for HDB account holders.

### **Envisioning Health Record Banks (Health Data Banks)**

A Health Data Bank, as noted above, is a secure, private- or public-sector institution. HDBs will offer secure, encrypted repository accounts that patients and other consumers own and control, and where they can aggregate, store, and analyze their health data. Health data includes (and is not limited to) encounter reports – institutional medical records – at clinician offices and hospitals, pharmaceutical data, and payment information related to health care. This information can be integrated using software at the HRB to create a lifetime, longitudinal, problem-oriented Personal Health Record (PHR), access to which consumers control.

Consumers can use their PHRs to help manage their interactions with the health care system and to help understand and manage their health care. HRBs will offer analytical and advisory services to help PHR account holders interpret what is in their lifetime records. Third parties may also offer complementary analytical services. HDB PHRs will also offer patients the ability to integrate new data from various providers as time goes by in order to keep their lifetime records updated, accurate, and instantly available.

When HRBA was organized in 2006, hospital and clinician *medical records* were the principal category of information that consumers might want to acquire for their PHRs. Today, consumers also seek to incorporate data from their own observations; suggestions, observations, and analysis from family, friends, and other advisors; and data from a wide, expanding array of personal digital devices that they can input to their PHRs.

At HRBA, we therefore use “Health Record Bank” and “Health Data Bank” interchangeably. Because HDB encompasses the more recent, widespread development of

personal digital devices that furnish *data* rather than traditional medical *records*, we use “HDB” throughout these comments. However, both terms convey the same concepts.

HRBA believes that HDBs will emerge as a major, essential, institutional component of the U.S. health industry. HDBs will form a new industrial sector.

HDBs will become key to engaging patients through convenience and trust. HDBs will substantially facilitate and accelerate data sharing under the Interoperability Rule. This will improve care outcomes, speed progress in research, enhance privacy and security (for example, by ameliorating patient matching problems for those patients who use HDBs), keep patients engaged through ease of use, and reduce costs throughout the health care market.

These comments reflect HRBA’s consistent advice to Congress in advance of the 21<sup>st</sup> Century Cures Act and to ONC in crafting its Interoperability Rule to follow the Cures Act’s system design specifications. Any observer who tracks HRBA’s comments to ONC<sup>2</sup> will recognize the core of HRBA’s systems design in the Rule.

Clinician burdens due to data system complexities also will be ameliorated when HDB PHR account information is readily available for import into hospital and medical office EHR systems consistent with 45 CFR 170.215. Reliable patient data with provenance, aggregated from diverse providers and readily searchable in problem-oriented PHRs, will support faster and safer care and reduce clinician burden.

Patients with HDB PHR accounts will also be able to participate voluntarily, and on a broad scale, in public health initiatives. Consumers will have instant access to their compiled, longitudinal health records, which can include contemporaneous patient observations. Consumers will thus be able to report voluntarily to clinicians and, as appropriate, public health authorities, to seek evaluation of symptoms, advice on potential treatments or vaccinations, and research projects related to public health emergencies. These PHR capabilities will complement mandatory public health reporting requirements by clinicians and other provider institutions. The NDH that CMS proposes will add to all these functions by supplying consumers with easily obtainable, accurate data about their providers.

Many employers, insurers, and government agencies will help consumers open and maintain HDB PHRs. They will help underwrite HDB accounts because consumers who use HDB PHRs will better manage their health and healthcare. They will enjoy better health, so generally lower total healthcare costs will result. These are key health care priorities for a nationwide health IT infrastructure as contemplated in section 3001(b) of the Public Health Service Act (PHSA). They illustrate the inherently efficient, superior systems design of integrating health data around the patient. That is the core systems advance that HDB PHRs represent, and will bring as a structural feature to U.S. health care and the health industry.

For all these reasons, Congress and state legislatures are likely, eventually, to consider how to encourage the private sector to invest in HDBs, and otherwise to make possible consumers’ rapid, pervasive adoption of HDB PHR accounts. Tax incentives and direct subsidies for HDB accounts are among the provisions to be explored. These considerations are likely to

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<sup>2</sup> HRBA’s comments are available at [www.healthbanking.org](http://www.healthbanking.org).

emerge as CMS implements the Cures Act in partnership with ONC by creating the means for consumer access to consolidated provider information.

Until the advent of the Cures Act and ONC's Interoperability Rule implementing it, there has been no affordable, reliable way to move health record data out of, between and among, and into disparate EHR systems in the U.S. And there has been no practical, widespread, systematic, secure, convenient way to move that data into the hands of consumers to use reliably and routinely. All that will begin to change as of January 1, 2023.

### **HDB Industry Regulation and Self-Regulation**

As a proponent of HDB PHRs since 2006, HRBA is an advocate both for industry self-regulation and standards of conduct and for federal regulation of HDBs and other private-sector repositories of consumers' health data. Federal regulation must be structured to keep bad actors from offering HDB services. At the same time, regulation must be tailored to allow HDBs to innovate continually in the storage, analytical, and advisory services they make available to consumers who use HDB PHRs and to employers who understand the advantages of encouraging (and in many cases subsidizing) PHR use by their employees. The availability of CMS's proposed NDH will be an important component of the federal regulatory framework that must be put in place to protect consumers who will rely on HDB services.

Government, industry, and the public will inevitably draw conclusions about privacy and other ethical factors attending the collection of medical record and other health data, and the circumstances under which that data can be communicated to whom and by whom. HRBA expects to participate in helping organize private sector development of these policies, and in helping to coordinate them with federal and state regulatory initiatives in the delivery of care, public health services, health equity, and medical research.

### **Conclusion**

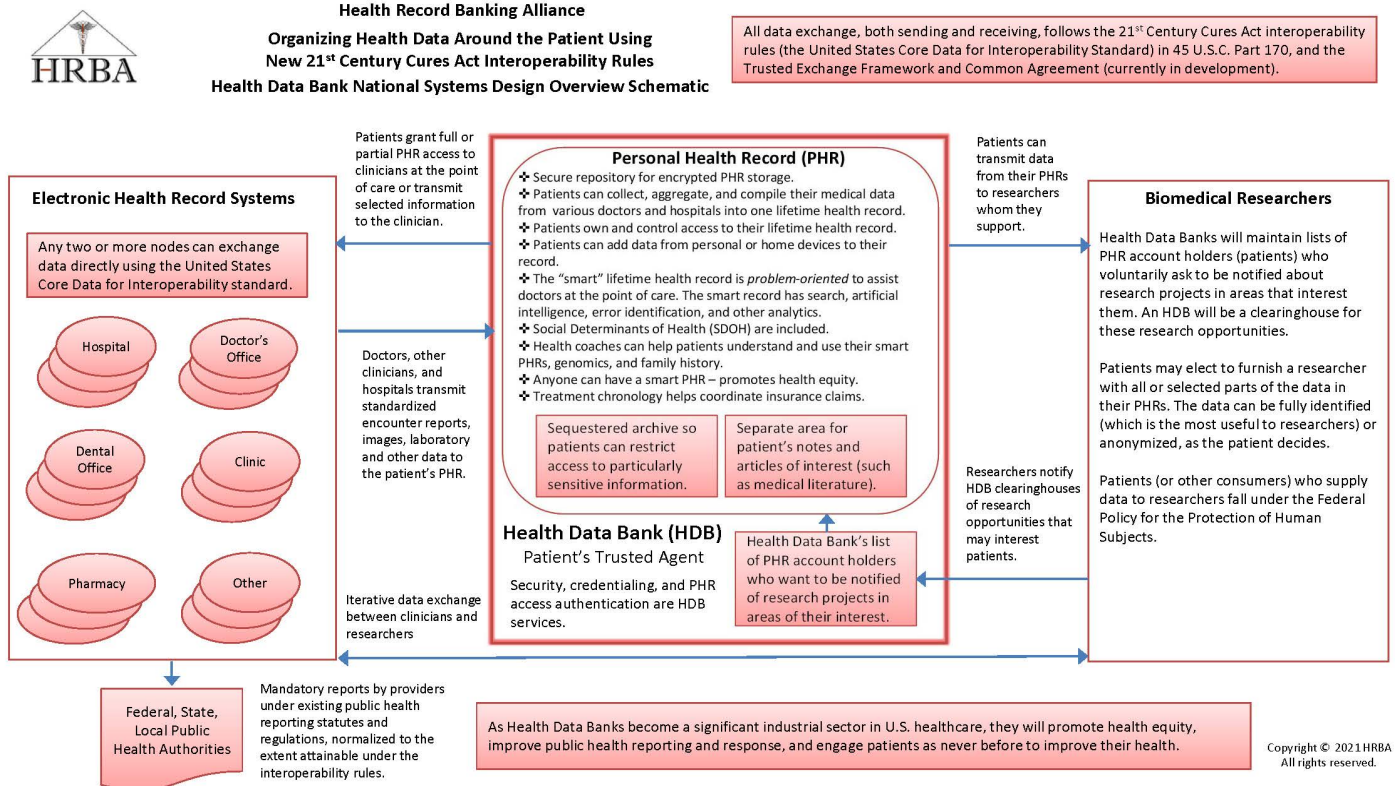
The patient-centric, integrative function of HDBs in an evolving nationwide health information network will encourage patient engagement on a wide scale, one not seen before. HDB PHRs by design will facilitate patients' secure and easy access to their health data. Advisory services such as health record social workers and AI applications will help patients understand the data in their Personal Health Records, highlight and help interpret critical information, and help patients manage their health and health care.

Health Data Banks (or Health Record Banks) are a patient-centric technology, really a bundle of technologies, that will become a significant structural segment of the U.S. health care industry. HDB adoption will grow as more consumers see the advantages of HDBs as trusted agents for aggregating and safeguarding their medical records and other health information. CMS's proposal to create and maintain the NDH will be a significant addition to the systems design for trusted health data exchange on a nationwide scale.

Respectfully submitted,  
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## Appendix

### Health Data Bank (Health Record Bank) Schematic Overview And Descriptive Summary



Please see accompanying text on the following page.



## Health Record Banking Alliance

### Organizing Health Data Around the Patient Using New 21<sup>st</sup> Century Cures Act Interoperability Rules

#### Health Data Bank National Systems Design Overview

A **Health Data Bank (HDB)**, also called a Health Record Bank) is an **integrated patient information services institution**. As a **trusted agent**, it offers a **secure repository** for each individual to collect and compile their **“interoperable”** digital health information in a **smart Personal Health Record (PHR)**. Individuals own and control their Personal Health Records, as in a bank checking account. With these **new information flows**, consumers will:

- exchange medical records and other health data in their Personal Health Records conveniently with doctors’ offices and hospitals for better, faster care; improve patient safety; and reduce information burden on physicians by supplying an aggregated, lifetime, searchable medical record for easy and immediate reference.
- control Personal Health Record access for doctors and hospitals; family, friends, and health coaches; medical researchers; members of the press; and others as they wish.
- use their Personal Health Records to help manage their health and healthcare, and to help shop for doctors, hospitals, and health insurance.
- view their Personal Health Records on smartphones, tablets, and other computers.

**Health Data Banks and Efficiency: Integrating health information around each patient** via HDBs is the most efficient way to aggregate and use **“interoperable”** health data under 21st Century Cures Act regulations. It is far more efficient and useful than a collection of “apps.”

**HRBA’s Education and Policy Advocacy:** HRBA advocates government policies promoting Health Data Banks as a **major new structural sector in U.S. health care**. This systems design includes a **national regulatory framework for Health Data Banks**.

**Health Data Banks and Health Equity:** Health Data Banks will promote **health equity** because **everyone can have a Personal Health Record**.

**Health Data Banks as Medical Research Clearinghouses:** Medical researchers cannot get enough patient data to make fast or sufficient progress. HDBs can be clearinghouses between patients and researchers. Patients can **voluntarily** list themselves with their HDBs to be informed of research projects they are interested in, and to which they want to **contribute or sell their data**. This also is a path to developing **national federated diagnostic and research databases** while respecting **patients’ privacy rights** (because patients are in control). Better research will improve treatment for acute, chronic, and orphan diseases.

**Health Data Banks, Security, and Patient Matching:** Security, credentialing, and patient authentication and efficient matching are systems design features of HDBs

**Advanced Features of Smart Personal Health Records:** Systems design features such as artificial intelligence (AI) and search capabilities, robust family history, and genomic analytics will deliver **problem-oriented data and analysis** to **mesh** with clinicians’ Electronic Health Record (EHR) systems **at the point of care**. Availability of this aggregated **reference record** will reduce burdens on clinicians while improving diagnosis, treatment, and patient outcomes.