

**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-9123-P**

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The Health Record Banking Alliance (“HRBA”)¹ offers comments in response to the Centers for Medicare and Medicaid Services’ request for information on a proposed rule to improve the electronic exchange of health care data and streamline processes related to prior authorization, while continuing CMS’s drive toward interoperability, and reducing burden in the health care market.

We are at the start of a multi-year process to implement ONC’s new interoperability rule. The goal is to put patients at the center of their care and in control of their health information. To that end, HRBA believes that Health Data Banks (“HDBs”) will emerge as a major, essential, institutional component of the U.S. health industry.

HDBs, by virtue of their structure and operating design, have unique utility. They can automatically gather, aggregate and compile, and integrate health information around patients without requiring their significant effort or attention. We emphasize that HDBs’ design and functions eliminate the need for patients to work to gather and compile their health data from various, disparate providers and other sources.

HDBs thus will become key to engaging patients through convenience. 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. We expand on this functionality in some detail below.

These comments reflect HRBA’s consistent advice to Congress in advance of the 21st Century Cures Act and to ONC in crafting its interoperability rule to follow the Cures Act’s system specifications. Any observer who tracks HRBA’s comments to ONC² will recognize the core of HRBA’s systems design in ONC’s final interoperability rule. These comments are submitted to CMS for the purpose of following through on those core design imperatives, consistent with the Cures Act.

¹ 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.

² HRBA’s comments are available at www.healthbanking.org.

Health Record Banks (Health Data Banks)

A Health Record Bank (HRB) is a secure, private-sector repository offering patients and other consumers encrypted accounts in which to store 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 Personal Health Record (PHR) that each consumer owns and controls.

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. HRB 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 and instantly available.

When HRBA was organized in 2006, hospital and clinician *medical records* were the principal category of information that consumers would 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 into 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.

Until the Cures Act and ONC’s announcement of rules to implement Cures Act-mandated record exchange and interoperability, medical record data in digital form could not be moved routinely, affordably, and securely among providers and patients. However, digital health data will become exchangeable, at an initial level of interoperability, after the transition to ONC’s announced Cures Act regulatory regime.

HRBA’s intention in these comments therefore is to inform readers at CMS about HDBs, why they are valuable, and why we anticipate that HDBs will become a significant sector of U.S. health care after the transition period to ONC’s new interoperability rules.

The New National Digital Health Data Exchange Standard: Health Data Banks for Patient-Owned and Controlled, Aggregated Lifetime Health Records as an Emerging Structural Feature of Health Care in the United States

Many policy and functional goals set forth by CMS in its proposals here will be substantially advanced when private sector health data banks (HDBs) emerge as a major, new, structural component of U.S. health care. As health data exchange in the U.S. becomes a regulated industry, HDBs will play a powerful part in bringing patient centricity to health

data. How will HDBs come into existence, and how will they improve patient identity and authentication?

The answer starts with ONC's new interoperability rules.

Consumers, using the new interoperability rules, will acquire, aggregate, and store lifetime health data in secure HDB PHR accounts they own and control. Consumers will use their PHR data and related application programming interfaces (APIs) to help manage their health and interactions with the health care system. They will be able to use their compiled, lifetime health data to shop for health care and health insurance, and, for example, to help streamline the process of securing prior authorizations for treatment. Having HDB PHR accounts also will facilitate consumers' sharing their data (sometimes anonymized, sometimes fully identified, as each patient wishes) with medical researchers pursuing projects that patients and their families care about.

Since 2006, HRBA has asserted to Congress, successive administrations, and to ONC the necessity for a mandatory, national, digital, health data exchange standard for U.S. healthcare (the "Exchange Standard"). We were gratified when HRBA-endorsed engineering design criteria for the Exchange Standard, along with supporting policy provisions, were specified in the 21st Century Cures Act, and then included, and greatly expanded upon, in ONC's interoperability rules.

HRBA recognized years ago that a national, mandatory Exchange Standard was the only feasible engineering path to make patient data in EHR systems exchangeable routinely, affordably, reliably, securely, and usefully among patients and clinicians. (In these comments, Electronic Health Record, or EHR, is used as a synonym for Electronic Medical Record, or EMR.) As the Exchange Standard is implemented and consumers' health data becomes easily exchangeable – sometimes spoken of as becoming "liquid" – patients will have an easy time gathering data from all their clinicians and other providers and consolidating it in their HDB PHRs.

For those purposes, HDBs will offer application programming interfaces (APIs) that comply with, and implement, the Exchange Standard, and specifically the implementation specifications in 45 CFR 170.215. HDBs will also offer a variety of PHR program features – for example, artificial intelligence (AI) analytical capabilities – that will help consumers manage their aggregated longitudinal health records. Depending on their business models and system designs, HDBs may also offer their PHR account holders advisory services such as Medical Record Social Worker consultation plans. These advisory services will be essential to help consumers understand the health data they receive from providers, aggregate it easily and reliably in their PHRs, use their PHRs to help make decisions, and use PHR data to help streamline insurance and payment functions.

Viewed in terms of systems design, HDBs' patient-centric orientation will use the Exchange Standard to interface smoothly and productively with EHR systems in hospitals, clinicians' offices, and elsewhere throughout U.S. health care. Hospital and clinician office EHR systems will routinely match their patient identification to patients' unique HDB PHR account identifiers. This is akin to account holder identification in the financial industry. Thus, for patients with HDB PHR accounts, patient authentication and credentialing will be reliable and efficient, a major improvement in patient safety. These patients will be able to

avoid the complexities and inevitable mis-identification problems associated with even the most accurate patient identity matching schemes.

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 PHRs, will support faster and safer care.

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.

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 that may be explored. These considerations are likely to emerge as CMS implements the Cures Act in partnership with ONC.

CMS may well ask why HDBs have not yet emerged in, much less been proposed as a significant structural component of, the health industry. After all, HDBs and PHRs as concepts offer a path to integrate health data around each patient, the most efficient way to organize patients' health information and make it useful.

The answer is that, 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 the 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.

There is ample proof of that historical reality. Examples include the futile, decades-long effort to enable the Department of Defense and the Department of Veterans Affairs to move health records back and forth between medical record systems serving military service members and those serving veterans; the failures of Google Health and Microsoft HealthVault; and the futility of various other demonstration projects.

That EMR systems began and grew with disparate technical designs in the U.S. is a historical reality. It was not until the Cures Act that a practical engineering solution was mandated to allow health data to move among these systems. The task now is to implement the Cures Act's engineering solution efficiently, and with policies that promote ease of use, reduction in clinician burden, capacity for infinite growth benefitting the clinic and the research laboratory, and engagement of consumers and the private sector – all with due regard for the practicalities of privacy, security, and the wide spectrum of consumer choice.

Reponses to CMS's Specific Requests for Information

CMS's draft proposed rule, beginning at p.188, requests comment in five areas:

- *Methods for Enabling Patients and Providers to Control Sharing of Health Information*
- *Electronic Exchange of Behavioral Health Information*
- *Reducing Burden and Improving Electronic Information Exchange of Documentation and Prior Authorization*
- *Reducing the Use of Fax Machines for Health Care Data Exchange*
- *Accelerating the Adoption of Standards Related to Social Risk Data*

HRBA's responses are as follows:

Methods for Enabling Patients and Providers to Control Sharing of Health Information

To explain the methods HDBs will use to enable patients and providers to control sharing of health information using PHRs as a hub, we first review how HDBs will operate as an emerging new sector of the health care industry in the U.S.

HDBs, as a basic, patient-centric, structural sector of the health industry, will function similarly to financial banks that offer checking and savings accounts. Patients will open lifetime PHR accounts in HDBs to aggregate and compile all their health data, including medical records of all their encounters, as well as their own observations and data from personal digital health devices.

We expect that HDB business models will offer substantial advisory services to patients in the interpretation, understanding, and use of their PHRs. Further, we anticipate that third-party advisory services for patients will enter the health industry marketplace. These third-party services will complement and in many cases compete with the PHR advisory options offered by HDBs. Consumers therefore will have available a spectrum of options to help them understand and use the medical record and other health information housed in their HDB PHRs.

Opening PHR accounts will require HDBs to vet every new account holder. The vetting process at most HDBs will be rigorous because of the sensitivity of medical record and other health data that consumers will aggregate, store, and use in their HDB PHRs. Account holder identity proofing will be a requisite for patients' secure and reliable use of their lifetime PHRs, particularly when granting clinician or payor access to some or all of their PHR data for treatment, payment, or research purposes.

Patients and other consumers who are vetted as part of establishing HDB PHR accounts will have secure account identifiers to authenticate themselves, credential themselves for health and health data transactions, and validate access to their health data accounts by clinicians, pharmacies, payors, researchers, and others as appropriate. Their HDB-facilitated data transfers will typically be highly secure. Moreover, if a consumer's HDB PHR is compromised – as happens with financial institution accounts – account numbers can be changed with relative ease and convenience.

HDBs thus rationalize the systems design for the secure sharing of PHR information between patients and providers. Providers will be required under 45 CFR 170.215 to transmit the digital report of each encounter to the patient's HDB PHR. These HDB systems software will aggregate the new encounter data with the patient's other health information, adding it to the lifetime PHR the patient owns and controls. Patients will be able to share all or particular parts of their longitudinal PHR with specified providers because they will control exports from, and access to, their PHRs.

Patient's information security is enhanced and privacy rights respected in this systems design, because the HDB acts as each patient's trusted agent and PHR information hub. The patient selects what information to share with providers; with family members, friends, and other caregivers, for example, in the context of connected care; or otherwise.

Consumers who use HDB PHRs will not be frustrated by instances of information blocking, because each consumer will have power to share (or not share) data directly from their PHR. That is, HDB PHRs will implement data segmentation according to patient consent as an integral design capability. Patients can elect to transmit all or portions of their aggregate PHR record or, alternatively, via consent, give providers plenary or select access to portions of their PHR. Facilitating data segmentation and patient consent as appropriate will be part of HDBs' client service functions as conceived and evolved in their business models.

As HDBs become known, and as more and more consumers opt to open HDB PHRs, the patient-controlled exchange of health data will support integrated care. Small, community-based providers will be on an equal footing with large providers when it comes to digital health information exchange to benefit and care for patients.

Electronic Exchange of Behavioral Health Information

How behavioral health providers interact with HDBs is a policy area in an early stage of development. It will require careful dialog among patient groups, clinician organizations, and government at the state and federal level. The practicalities of behavioral health diagnosis and treatment, as well as ethical considerations and differing state regulatory policies, pose challenges. Differing conceptions of privacy rights regarding behavioral health data impose significant additional complications. HRBA is confident, however, that policies and system features for coordinated care in behavioral health will emerge as the HDB industry begins to operate on a wide scale, more and more consumers establish PHRs at HDBs, and HDBs as a whole become a significant sector in the U.S. health care industry.

In that context, however, HRBA would strongly encourage CMS to facilitate behavioral health providers' obtaining software that they can use to receive data using FHIR

APIs, even though that is not a full EHR implementation. The rationale for such a policy is that availability of even partial data systems capacities will facilitate use of patient-generated and caregiver-generated data in the diagnosis and treatment of behavioral health conditions.

HRBA also endorses robust standards for data segmentation and control, as discussed in the previous section. We expect that, the greater control available to patients, the greater the overall sharing of information will be. Patients' ability to control dissemination to specific providers regarding specific periods of time, specific encounters, specific diagnoses, or specific therapies will encourage an increase in the information patients make available to behavioral health professionals, compared to what is common today. The expanded availability of information to treat behavioral health conditions will be increasingly critical, as current trends indicate that behavioral health issues will become more fully integrated into the overall health care delivery process.

*Reducing Burden and Improving Electronic Information Exchange of Documentation and Prior Authorization; and
Reducing the Use of Fax Machines for Health Care Data Exchange*

CMS can expect HDBs' capacities for maintaining lifetime medical records and associated health data to effect a significant reduction over time in clinician and payer overhead required for prior authorization. A major administrative burden in the prior authorization process arises from requirements to obtain information about a patient's complete relevant medical record, not just the component held by the provider requesting authorization. With a patient's lifetime record in an HDB, a provider to whom a patient has given access will have available comprehensive documentation relevant to the patient's condition. This will eliminate the need to request information from the patient's past health care providers. Availability of a lifetime record thus avoids the need for additional information exchanges in this context.

More generally, HRBA's responses to these two information request categories go together, and flow from the systems design capabilities of HDBs as an anticipated new structural sector in U.S. health care. HDBs will be digital enterprises. PHRs housed in HDBs will have storage, retrieval, and communications capabilities designed for ease of use in complying with the national Exchange Standard embodied in 45 CFR 170.215. Thus, exchanging data in PHRs and receiving encounter information from patients' diverse providers will be routine, a feature of every HDB's systems functioning and business model.

Note that the Exchange Standard implements the Cures Act's "computable" requirement. Instantiated in FHIR, the receiving capabilities of EHR systems in hospitals and clinician offices (among other receiving facilities) will be required under 45 CFR 170.215 to have pointers that route incoming data to the appropriate functional EHR storage locations or nodes. This regulatory requirement is fundamental to operation of the Exchange Standard. Incorporating it in the operating design of all certified EHR systems, via digital automation, will reduce the data exchange resource burden under ONC's interoperability rule. It will, as noted earlier, make data entry from provider encounters an automated convenience, and so a non-issue and non-burden, for patients. It will also reduce clinician burden in receiving, categorizing, retrieving, and analyzing medical record inputs from external sources.

Exchange Standard certification requirements will also reduce burdens on consumers and their advisors in navigating and using HDB PHRs. Data imported into consumers' PHRs will be routed, using internal system communications protocols in standardized ways, to the appropriate PHR nodes and storage locations. Thus patients, caregivers, and others will be able to retrieve and view data conveniently, in familiar PHR categories they expect, in consistent, disciplined patterns.

The capacity to exchange PHR information in the Cures Act Exchange Standard format will simplify and accelerate "interoperable" data exchange and documentation requirements. That will be true, as noted above, for documentation necessary for prior authorizations (among so many other required data exchange categories). And these secure, routine, hassle-free data exchange capacities of HDB PHRs will herald abandonment of fax exchanges as obsolete in the health industry.

Accelerating the Adoption of Standards Related to Social Risk Data

HDBs can play a unique role in facilitating collection of social risk data. HDBs offer continuous channels of communication between health care providers and patients and their caregivers. These are not limited to office encounters or weekly visits. This in turn makes it possible for health care providers to obtain a more accurate depiction of a patient's day-to-day experiences, so that social risk factors may be more accurately assessed.

In developing standardized ways to record risk data, government and the private sector will cooperate to identify and categorize data relevant to patient social risk. HDBs will adopt these standards as they are being developed, for example, by the Gravity Project FHIR Accelerator.

The goal of standardizing risk data elements uniformly will be made easier by the systems design features of HDBs. Patient-controlled PHRs at HDBs offer opportunities to add risk and other public health data into each participating patient's lifetime, longitudinal record. HDB analytical tools will be capable of integrating social risk data for a variety of purposes including diagnosis and treatment. The extent to which risk data is disclosed will be subject to each patient's privacy preferences, a consequence of the fundamental HDB design principle of patient control.

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.

Government, industry, and the public will work to 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, 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.

This discussion demonstrates how integrating health data around each patient (or consumer) is the most efficient way to achieve a nationwide health information network as envisioned in section 3001(b) of the PHSA. It is enabled by ONC's implementation of the nationwide digital health data Exchange Standard as outlined, and specified at a high level, in the Cures Act, and by CMS's support and adoption of those same standards and rules.

Enabled by the Exchange Standard, 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 policies to implement the Cures Act in concert with ONC will benefit HDBs' emergence.

Respectfully submitted,

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